UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN LOSARTAN AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler Hon. Joel Schneider **Jury Trial Demanded** **First Amended Consolidated Losartan Class Action Complaint**

FIRST AMENDED CONSOLIDATED LOSARTAN CLASS ACTION COMPLAINT

1. COME NOW, the Consumer and Third Party Payor ("TPP") Plaintiffs (collectively the "Class Plaintiffs"), who file this First Amended Consolidated Losartan Economic Loss Class Action Complaint ("Master Losartan Class Complaint")[1] against the below-enumerated Defendants.

I. INTRODUCTION

2. This case arises from adulterated, misbranded, and unapproved losartan-containing drugs ("LCDs") that were designed, manufactured, marketed, distributed, packaged, and sold by Defendants (identified and defined *infra* at Part II.C-H) in the United States, and which have been and remain the subject of one of the largest ongoing contaminated drug recalls ever in the United States. These LCDs are non-merchantable, and are not of the quality represented by Defendants named herein.

[1] This is one of three losartan master complaints being filed in this multi-district litigation. The filing of three master complaints is to streamline the pleadings and issues for the parties' mutual convenience only. Consumer Class Plaintiffs do not waive any claims that are not raised herein, or that are asserted in another master complaint.

3. Originally marketed under the brand names Cozaar (Losartan Potassium), Tozaar (Hydrochlorothiazide and Losartan), and Tozam (Amlodipine and Losartan), losartan is a prescription medication mainly used for the treatment of high blood pressure, diabetic kidney disease, congestive heart failure, and left ventricular enlargement, among other issues.

4. Losartan and its combination therapy are the generic versions of the registered listed drugs ("RLDs") Cozaar, Tozaar, and Tozam. However, due to manufacturing defects originating from overseas laboratories, Defendants' generic formulations have become contaminated with various nitrosamine contaminants and impurities, as set forth herein.

5. The Class Plaintiffs bring this economic-loss action on behalf of LCD consumers and third-party payors who paid or made reimbursements for Defendants' adulterated, misbranded, and/or unapproved LCDs illegally manufactured, sold, labeled, marketed, and distributed in the United States as FDA-approved generic versions of Cozaar, Tozaar and Tozam. Defendants' generic LCDs were in fact not FDA-approved generic versions of these drugs, and were instead of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with IARC- and EPA-listed probable human carcinogens known as N-nitrosodiethylamine ("NDEA") and N-Nitroso N-Methyl 4-Amino Butyric Acid ("NMBA").

6. Beginning in late 2018 and continuing through September of 2019, the United States Food & Drug Administration ("FDA") announced recalls of Defendants' LCDs due to levels of NDEA and/or NMBA that exceed acceptable levels set by the FDA.

7. Defendants have been illegally manufacturing, selling, labeling, marketing and distributing the misbranded and/or adulterated LCDs in the United States for years, reaping many millions of dollars in profit, while not disclosing to Class Plaintiffs the true nature of the LCDs.

8. At all times during the period alleged herein, Defendants represented and warranted to consumers and TPPs that their generic LCDs were therapeutically equivalent to and otherwise the same as their RLDs, were fit for their ordinary uses, and were manufactured and distributed in accordance with applicable laws and regulations.

9. However, for years, Defendants willfully ignored warnings signs regarding the operating standards at several of the overseas manufacturing plants where Defendants' generic LCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded LCDs for purchase and reimbursement in the United States by U.S. consumers and TPPs.

10. The Class Plaintiffs paid for or made reimbursements for generic LCDs that were illegally and willfully introduced into the market by Defendants, causing the Plaintiff Class(es) to sustain economic damages. Defendants' generic LCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs since at least 2012. Defendants' conduct also constitutes actionable common law fraud, consumer fraud, and other violations of state and federal law as set forth herein.

11. The LCDs Defendants sold to Class Plaintiffs were worthless due to the presence of nitrosamines which rendered the LCDs unfit for use and for human consumption, requiring recall by the FDA. Class Plaintiffs would not have purchased the LCDs had they known the true nature of the LCDs.

12. Further, Class Plaintiffs suffered injury in having to purchase replacement medications, while not receiving the full benefit of the LCDs they purchased. Specifically, Class Plaintiffs were required to cease using LCDs they had paid for and repurchase a replacement medication. Had the LCDs been properly manufactured, Class Plaintiffs would have received the benefit of

the full bottle of the product they purchased and would not have incurred the cost of paying for replacement medication.

II. PARTIES

A. Consumer Class Representatives

13. Plaintiff Ira Sanders is a North Carolina resident and citizen. During the class period, Plaintiff Sanders paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Sanders purchased LCDs from the Torrent Defendants (using API manufactured by the Hetero Defendants). Plaintiff Sanders purchased his LCDs from Harris Teeter Pharmacy. On several occasions, Plaintiff Sanders was prescribed and purchased LCDs bearing the NDC numbers 13668-0115-10 and 13668-0115-30, a 100 mg dose. Plaintiff Sanders originally learned about the recall by receiving notices from Aetna and Harris Teeter. The Aetna letter, dated January 3, 2019, warned Plaintiff Sanders that "[t]here's a recall for a drug you may use," due to "**an unexpected impurity [that] was found in these products that may cause health risks**" (bold in original). The Aetna letter further warned that "**[t]here's a potential health hazard or safety risk if you're using this product**" (bold in original). The Aetna letter further urged Plaintiff Sanders to "**[p]lease call your doctor right away for advice if you may be using affected product**" (bold in original). Plaintiff Sanders reviewed the recall letter, cross referenced the affected NDC numbers with the NDC numbers of the medications he received, and determined that he had been consuming the contaminated LCDs manufactured by Torrent, and sold by Harris Teeter. Defendants expressly and impliedly warranted to Plaintiff Sanders that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Sanders purchased a product that was not the same as the RLD. When purchasing his LCDs from

Defendants, Plaintiff Sanders reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Sanders relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Sanders known the product was not the same as the RLD, Plaintiff Sanders would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Sanders would not have paid for Defendants' LCDs.

14. Plaintiff Solomon Zeller is a Florida resident and citizen. During the class period, Plaintiff Zeller paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Zeller was prescribed LCDs manufactured and distributed by the Torrent Defendants (using API from the Hetero Defendants), which he purchased from CVS in Boca Raton, Florida. Plaintiff Zeller originally learned about the recall by receiving notices from United Healthcare and CVS. The CVS letter, dated January 7, 2019, provided Plaintiff Zeller with the NDC numbers and lots affected by the recall. Plaintiff Zeller reviewed the recall letters, cross referenced the affected NDC numbers with the NDC number of the medication he purchased, and determined that he was prescribed, purchased, and had been consuming one of the contaminated LCDs manufactured by Torrent, and sold by CVS. Defendants expressly and impliedly warranted to Plaintiff Zeller that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Zeller purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Zeller reviewed the accompanying labels and

disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Zeller relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Zeller known the product was not the same as the RLD, Plaintiff Zeller would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Zeller would not have paid for Defendants' LCDs.

15. Plaintiff Joseph Glenn Cummings is a Mississippi resident and citizen. During the class period, Plaintiff Cummings paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Cummings was prescribed LCDs manufactured and distributed by Defendant Torrent (using API from the Hetero Defendants), which he purchased from Kroger in Richland, Mississippi. Plaintiff Cummings was prescribed and purchased losartan medication bearing NDC number 13668-409-10, a 50 mg dose. Each time, Plaintiff Cummings paid a co-pay of $12.92 for the contaminated LCDs. After learning of the recall, Plaintiff Cummings called Kroger, who identified his medication as subject to the recall. Defendants expressly and impliedly warranted to Plaintiff Cummings that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Cummings purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Cummings reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the

name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Cummings relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Cummings known the product was not the same as the RLD, Plaintiff Cummings would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Cummings would not have paid for Defendants' LCDs.

16. Plaintiff Rosa Burton is a Florida resident and citizen. During the class period, Plaintiff Burton paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Burton was prescribed LCDs manufactured and distributed by Defendant Torrent, which she purchased from The Pharmacy Store in Apopka, Florida. On several occasions in 2018, but specifically on October 22, 2018, Plaintiff Burton received LCDs bearing NDC number 13668-0118-10, a 100 mg dose. After hearing about the recall, Plaintiff Burton cross-referenced the affected NDC numbers with the NDC number of the medication she purchased, and determined that she was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Torrent, and sold by The Pharmacy Store. Defendants expressly and impliedly warranted to Plaintiff Burton that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Burton purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Burton reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from

contaminants and defects. Plaintiff Burton relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Burton known the product was not the same as the RLD, Plaintiff Burton would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Burton would not have paid for Defendants' LCDs.

17. Plaintiff Delphine Harris is a Texas resident and citizen. During the class period, Plaintiff Harris paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Defendants expressly and impliedly warranted to Plaintiff Harris that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Harris purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Harris reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Harris relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Harris known the product was not the same as the RLD, Plaintiff Harris would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Harris would not have paid for Defendants' LCDs.

18. Plaintiff Damita Owens is a New York resident and citizen. During the class period, Plaintiff Owens paid money for one or more of Defendants' LCDs, including purchases of LCDs

manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Owens was prescribed LCDs manufactured and distributed by the Torrent Defendants, which she purchased from Duane Reade in Brooklyn, New York. On several occasions in 2018 and 2019, Plaintiff Owens received LCDs bearing the NDC number 13668-0116-90, at a 50 mg dose. Plaintiff Owens paid a co-pay for each fill of the medication. Plaintiff Owens originally learned about the recall by receiving a notice from Walgreens[2]. The Walgreens letter, dated March 2019, warned Plaintiff Owens that she may have "received one or more prescriptions for Losartan products manufactured by Torrent Pharmaceuticals from a Walgreens pharmacy." The letter continued that Torrent "is voluntarily recalling these items due to the detection of a trace amount of N-Nitrosodimethlamine (NDEA)," which is a substance that "has been classified as a probable human carcinogen." The Walgreens letter also provided Plaintiff Owens with the NDC numbers and lots affected by the recall. Plaintiff Owens reviewed the recall letter, cross referenced the affected NDC numbers with the NDC number of the medication she purchased, and determined that she was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Torrent, and sold by Daune Reade. Defendants expressly and impliedly warranted to Plaintiff Owens that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Owens purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Owens reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from

[2] Duane Reade became part of Walgreens in 2010. See https://www.walgreens.com/topic/duane-reade/duane-reade.jsp (last visited 1/15/21).

contaminants and defects. Plaintiff Owens relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Owens known the product was not the same as the RLD, Plaintiff Owens would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Owens would not have paid for Defendants' LCDs.

19. Plaintiff Glenn Roddey is a Florida resident and citizen. During the class period, Plaintiff Roddey paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Mr. Roddey purchased his LCDs from Defendant Walmart. After hearing about the recall, Plaintiff Roddey cross referenced the affected NDC numbers with the NDC numbers of the medications he purchased, and determined that he was prescribed, purchased, and had been consuming the contaminated losartan medications manufactured, distributed, and sold by Defendants Camber, Hetero, and Legacy. Specifically, Plaintiff Roddey had been purchasing contaminated losartan medication bearing NDC numbers 68645-579-54 and 31722-702-90. When picking up his losartan medication from Walmart, Plaintiff Roddey paid a copay for numerous fills of the contaminated medication. Plaintiff Roddey originally learned about the recall by receiving a notice from Walmart. The Walmart letter, dated February 28, 2019, warned Plaintiff Roddey that there was an "important voluntary recall concerning this product" due to the detection of "N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in the active pharmaceutical ingredient, manufactured by Hetero Labs Limited, Unit I." Defendants expressly and impliedly warranted to Plaintiff Roddey that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Roddey purchased a product that was not the same

as the RLD. When purchasing his LCDs from Defendants, Plaintiff Roddey reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Roddey relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Roddey known the product was not the same as the RLD, Plaintiff Sanders would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Roddey would not have paid for Defendants' LCDs.

20. Plaintiff Donald Melton is a Missouri resident and citizen. During the class period, Plaintiff Melton paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Specifically, Plaintiff Melton purchased and used LCDs manufactured by Hetero and Camber and repackaged by Legacy. Plaintiff Melton purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Melton that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Melton purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Melton reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Melton relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the

bargain. Had Plaintiff Melton known the product was not the same as the RLD, Plaintiff Melton would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Melton would not have paid for Defendants' LCDs.

21. Plaintiff William Kolacek is a Florida resident and citizen. During the class period, Plaintiff Kolacek paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Kolacek was prescribed LCDs manufactured by Defendants Camber and Hetero, repackaged and distributed by Defendant Legacy, and sold by Walmart. On June 28, 2018, October 2, 2018, and December 18, 2018, Plaintiff Kolacek purchased losartan-containing medication at a 100 mg dose, bearing NDC number 68645-0579-54. Each time, Plaintiff Kolacek paid a co-pay of $5.00 for the medication. After hearing about the recall, Plaintiff Kolacek cross referenced the affected NDC numbers with the NDC number of the medications he purchased, and determined that he was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Camber and Hetero, repackaged and distributed by Legacy, and sold by Walmart. Defendants expressly and impliedly warranted to Plaintiff Kolacek that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Kolacek purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Kolacek reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Kolacek relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these

representations and warranties were part of the basis of the bargain. Had Plaintiff Kolacek known the product was not the same as the RLD, Plaintiff Kolacek would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Kolacek would not have paid for Defendants' LCDs.

22. Plaintiff Helen Johnson is a Florida resident and citizen. During the class period, Plaintiff Johnson paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Johnson was prescribed contaminated losartan-containing medications manufactured, distributed and sold by Camber and Hetero. Specifically, Plaintiff Johnson was prescribed and purchased losartan medication bearing NDC number 31722-701-90, a 50 mg dose. When filling her prescription on February 11, 2019, Plaintiff Johnson paid a copay of $10.00 for the contaminated medication. After filling her prescription, Plaintiff Johnson received a letter from Walmart indicating that her medication was being recalled due to NMBA contamination, and instructing her to consult with her physician regarding alternative treatment options. Defendants expressly and impliedly warranted to Plaintiff Johnson that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Johnson purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Johnson reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Johnson relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Johnson known the product was not the same as the RLD, Plaintiff

Johnson would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Johnson would not have paid for Defendants' LCDs.

23. Plaintiff John Cox is an Arizona resident and citizen. During the class period, Plaintiff Cox paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Mr. Cox's LCDs were manufactured by Defendants Hetero Drugs, Limited and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. He purchased his medication from Walmart. Defendants expressly and impliedly warranted to Plaintiff Cox that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Cox purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Cox reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Cox relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Cox known the product was not the same as the RLD, Plaintiff Cox would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Cox would not have paid for Defendants' LCDs.

24. Plaintiff Darlene Hugg McCauley is an Arkansas resident and citizen. During the class period, Plaintiff Hugg McCauley paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra

Part III.). Ms. Hugg McCauley's LCDs were manufactured by Defendants Hetero Drugs, Limited and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. She purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Hugg McCauley that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Hugg McCauley purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Hugg McCauley reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Hugg McCauley relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Hugg McCauley known the product was not the same as the RLD, Plaintiff Hugg McCauley would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Hugg McCauley would not have paid for Defendants' LCDs.

25. Plaintiff Jean Ellen Thomas is a Virginia resident and citizen. During the class period, Plaintiff Thomas paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Thomas' LCDs were manufactured by Defendants Hetero Drugs, Limited and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. She purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Thomas that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Thomas purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants,

Plaintiff Thomas reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Thomas relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Thomas known the product was not the same as the RLD, Plaintiff Thomas would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Thomas would not have paid for Defendants' LCDs.

26. Plaintiff La'Vette Howard is a Louisiana resident and citizen. During the class period, Plaintiff Howard paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Howard's LCDs were manufactured by Defendants Hetero Drugs, Limited and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. She purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Howard that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Howard purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Howard reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Howard relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Howard

known the product was not the same as the RLD, Plaintiff Howard would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Howard would not have paid for Defendants' LCDs.

27. Plaintiff Dominick J. Nicastro Sr. is a New Jersey resident and citizen. During the class period, Plaintiff Nicastro paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Nicastro's LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Nicastro purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Nicastro that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Nicastro purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Nicastro reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Nicastro relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Nicastro known the product was not the same as the RLD, Plaintiff Nicastro would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Nicastro would not have paid for Defendants' LCDs.

28. Plaintiff Deborah A. Payne is a Mississippi resident and citizen. During the class period, Plaintiff Payne paid money for one or more of Defendants' LCDs, including purchases of LCDs

manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Payne's LCDs were manufactured by Defendants Hetero Drugs. Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. She purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Payne that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Payne purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Payne reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Payne relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Payne known the product was not the same as the RLD, Plaintiff Payne would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Payne would not have paid for Defendants' LCDs.

29. Plaintiff Eugene Tonkovic is a Missouri resident and citizen. During the class period, Plaintiff Tonkovic paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Tonkovic's LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Tonkovic purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Tonkovic that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Tonkovic purchased a product that was not the same as the RLD. When purchasing his LCDs from

Defendants, Plaintiff Tonkovic reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Tonkovic relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Tonkovic known the product was not the same as the RLD, Plaintiff Tonkovic would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Tonkovic would not have paid for Defendants' LCDs.

30. Plaintiff Alicia Degracia is a California resident and citizen. During the class period, Plaintiff Degracia paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Degracia was prescribed LCDs manufactured by Defendants Camber and Hetero, and repackaged and distributed by Defendant Legacy, and sold by Walmart. On August 23, 2018, November 2, 2018, and February 5, 2019, Plaintiff Degracia purchased losartan-containing medication at a 100 mg dose, bearing NDC number 68645-0579-54. Plaintiff Degracia paid a co-pay of at least $10.00 for each fill of the medication. After hearing about the recall, Plaintiff Degracia cross referenced the affected NDC numbers with the NDC number of the medications she purchased, and determined that she was prescribed, purchased, and had been consuming one of the contaminated medications manufactured by Camber and Hetero, and repackaged and distributed by Legacy. Defendants expressly and impliedly warranted to Plaintiff Degracia that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Degracia

purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Degracia reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Degracia relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Degracia known the product was not the same as the RLD, Plaintiff Degracia would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Degracia would not have paid for Defendants' LCDs.

31. Plaintiff David Gipson is an Illinois resident and citizen. During the class period, Plaintiff Gipson paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Gipson's LCDs were manufactured by Hetero Drugs Ltd. and Camber Pharmaceuticals, Inc. Mr. Gipson purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Gipson that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Gipson purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Gipson reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Gipson relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these

representations and warranties were part of the basis of the bargain. Had Plaintiff Gipson known the product was not the same as the RLD, Plaintiff Gipson would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Gipson would not have paid for Defendants' LCDs.

32. Plaintiff Thomas Ambrose is a Florida resident and citizen. During the class period, Plaintiff Ambrose paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Ambrose's LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Ambrose purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Ambrose that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Ambrose purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Ambrose reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Ambrose relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Ambrose known the product was not the same as the RLD, Plaintiff Ambrose would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Ambrose would not have paid for Defendants' LCDs.

33. Plaintiff Rosie Roberts is a Missouri resident and citizen. During the class period, Plaintiff Roberts paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Roberts' LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Roberts purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Roberts that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Roberts purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Roberts reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Roberts relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Roberts known the product was not the same as the RLD, Plaintiff Roberts would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Roberts would not have paid for Defendants' LCDs.

34. Plaintiff Patricia Bellin is a Wisconsin resident and citizen. During the class period, Plaintiff Bellin paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Bellin's LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc. Plaintiff Bellin purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Bellin that their respective generic LCDs were the same as their RLDs. But

in fact, Plaintiff Bellin purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Bellin reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Bellin relied on these representations and warranties in deciding to purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Bellin known the product was not the same as the RLD, Plaintiff Bellin would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Bellin would not have paid for Defendants' LCDs.

35. Plaintiff Lorna Anderson-Dawes is a Pennsylvania resident and citizen. During the class period, Plaintiff Anderson-Dawes paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Anderson-Dawes' LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Anderson-Dawes purchased her LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Anderson-Dawes that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Anderson-Dawes purchased a product that was not the same as the RLD. When purchasing her LCDs from Defendants, Plaintiff Anderson-Dawes reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Anderson-Dawes relied on these representations and warranties in deciding to

purchase her LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Anderson-Dawes known the product was not the same as the RLD, Plaintiff Anderson-Dawes would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Anderson-Dawes would not have paid for Defendants' LCDs.

36. Plaintiff Kevin Stolte is an Iowa resident and citizen. During the class period, Plaintiff Stolte paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Stolte's LCDs were manufactured by Hetero Drugs, Ltd. and Camber Pharmaceuticals, Inc., and repackaged by Defendant Legacy. Plaintiff Stolte purchased his LCDs from Walmart. Defendants expressly and impliedly warranted to Plaintiff Stolte that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Stolte purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Stolte reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Stolte relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Stolte known the product was not the same as the RLD, Plaintiff Stolte would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Stolte would not have paid for Defendants' LCDs.

37. Plaintiff Gary Roark is a Ohio resident and citizen. During the class period, Plaintiff Roark paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Plaintiff Roark was prescribed LCDs manufactured and distributed by Defendants, and sold by OptumRX. After hearing about the recall, Plaintiff Roark cross referenced the affected NDC numbers with the NDC numbers of the medications he purchased, and determined that he was prescribed, purchased, and had been consuming the contaminated LCDs manufactured, distributed, and sold by Defendants Macleods and Hetero. Plaintiff Roark was prescribed LCDs manufactured and distributed by Defendants, and sold by OptumRX. After hearing about the recall, Plaintiff Roark cross referenced the affected NDC numbers with the NDC numbers of the medications he purchased, and determined that he was prescribed, purchased, and had been consuming the contaminated losartan medications manufactured, distributed, and sold by Defendants Macleods and Hetero. Defendants expressly and impliedly warranted to Plaintiff Roark that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Roark purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Roark reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Roark relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Roark known the product was not the same as the RLD, Plaintiff Roark would not have paid for Defendants'

LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Roark would not have paid for Defendants' LCDs.

38. Plaintiff Argyre S. Patras is a Washington resident and citizen. During the class period, Plaintiff Patras paid money for one or more of Defendants' LCDs, including purchases of LCDs manufactured, distributed, or sold by the Hetero Defendants (as defined infra Part III.). Defendants expressly and impliedly warranted to Plaintiff Patras that their respective generic LCDs were the same as their RLDs. But in fact, Plaintiff Patras purchased a product that was not the same as the RLD. When purchasing his LCDs from Defendants, Plaintiff Patras reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were the bioequivalent of the name-brand medication, and were properly manufactured and free from contaminants and defects. Plaintiff Patras relied on these representations and warranties in deciding to purchase his LCDs from Defendants, and these representations and warranties were part of the basis of the bargain. Had Plaintiff Patras known the product was not the same as the RLD, Plaintiff Patras would not have paid for Defendants' LCDs. Likewise, had Defendants' deception about the impurities within their products been made known earlier, Plaintiff Patras would not have paid for Defendants' LCDs.

B. <u>The Third Party Payor ("TPP") Class Representatives</u>

39. Plaintiff MSP Recovery Claims, Series LLC ("MSPRC") is a Delaware series limited liability company with its principal place of business in Coral Gables, Florida. MSPRC's limited liability company agreement provides for the establishment of one or more specific Series. All records of all Series are maintained together with all assets of MSPRC.

40. As detailed below, certain healthcare benefit providers have assigned their recovery rights to assert the claims alleged in this Complaint to Series LLCs of MSPRC. Pursuant to MSPRC's limited liability agreement, all rights arising from the assignment to its series (including the assignments discussed below), along with the right to bring any lawsuit in connection with that assignment (including those below), belong to MSPRC. As such, MSPRC has the right and power to sue defendants to recover the payments at issue in this action.

41. Certain series of MSPRC have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assignors' health plan members and enrollees. These assignments authorize the series and, in turn MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. MSPRC alleges the assignments at issue below.

42. On March 20, 2018, Group Health Incorporated and Health Insurance Plan of Greater New York (otherwise known as "EmblemHealth" or "Emblem") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of their enrollees under Medicare Parts A, B, and D to Series 16-08-483, a designated series of MSPRC. Specifically, the assignments provide the following:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

43. On May 12, 2017, Summacare, Inc. ("Summacare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to MSP Recovery, LLC ("MSP Recovery"). Specifically, the assignment provides the following language:

> [Summacare] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [Summacare's] right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [Summacare] that [Summacare] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [Summacare] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

44. On June 12, 2017, MSP Recovery irrevocably assigned all rights acquired under the Summacare Assignment to Series 16-11-509, a designated series of MSPRC:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [claims] (and all proceeds and products thereof) as such terms are defined in the Recovery Agreement dated May 12, 2017, by and among [Summacare] . . . and [MSP Recovery] . . . .

45. Summarcare consented to, acknowledged, approved, and ratified the assignment from MSP Recovery to Series 16-11-509, which is memorialized in a letter dated September 5, 2018.

46. On March 20, 2018, Connecticare, Inc. ("Connecticare") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its enrollees under Medicare Parts A, B, and D to Series 15-09-157, a designated series of MSPRC. Specifically, the assignment provides the following language:

> Assignor hereby irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all [claims against third parties], whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may

> have had, or has asserted against any party in connection with the [claims] and all rights and claims against primary payers and/or . . . third parties that may be liable to Assignor arising from or relating to the [claims], including claims under consumer protection statutes and laws, and all information relating thereto, as may be applicable.

47. MSPRC is only asserting claims based on the above assignments. Collectively, Emblem, Connecticare, and Summacare shall be referred to as the "Assignors."

48. Defendants have manufactured and distributed the LCDs throughout the United States, for which consumers made co-payments, and TPPs paid. Specifically, the Assignors paid for LCDs listed as recalled by the United States Food and Drug Administration and that were manufactured, distributed, or sold by the Defendants.

49. Plaintiff Maine Automobile Dealers Association, Inc. Insurance Trust is a duly organized and existing 501(c)(9) tax-exempt trust that qualifies as a multiple employer welfare benefit plan or arrangement established or maintained for the purpose of offering or providing health benefits, including prescription drug coverage, to the employees of multiple employers and to their beneficiaries under the authority of the Maine Multiple-Employer Welfare Arrangements law, Title 24-A, Chapter 81, §§ 6601-6616 of the Maine Revised Statutes Annotated and the Employee Retirement Income Security Act of 1974. The Trust was organized in Maine and has its principal place of business in Maine.

50. The Trust administers a multiple-employer welfare arrangement for the sole purpose of funding a plan of benefits, both on a self-funded basis and through the purchase of policies of insurance.

51. The Trust provides health benefit coverage, including a prescription drug benefit, to its members. The Trust's members received prescriptions for and it paid for LCDs listed as recalled

by the United States Food and Drug Administration and that were manufactured, distributed, or sold by Defendants (as defined *infra* Part II.C).

C. The Hetero Defendants

52. Defendants are comprised of entities at various points in the manufacture, labeling, packaging, and distribution chain.

53. The Hetero Defendants are organized by the distribution level at which they principally operate, beginning with the highest level, the active pharmaceutical ingredient ("API") level. Generally, the losartan API is manufactured and sold to finished-dose manufacturers, who then distribute the finished product to labelers/distributors, as well as repackagers, who then distribute and sell the LCDs to pharmacy retailers. Pharmacy retailers then sell the LCDs the consumers, including the Class Plaintiffs. The inclusion of certain Defendants in this section does not mean they are not properly classifiable as another type of defendant, or vice versa (e.g., a Defendant listed in this subsection may also be a distributor; a Defendant listed in the distributor subsection may also be an API manufacturer).

i. API-Level Hetero Entities

54. Defendant Hetero Labs, Ltd. ("Hetero Labs") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad – 500 018, Telangana, India. Hetero Labs on its own and/or through its subsidiaries regularly conducts business in New Jersey and throughout the United States and its territories and possessions. At all times material to this action, Hetero Labs has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic LCDs throughout the United States.

55. Defendant Hetero Drugs, Limited ("Hetero") is a foreign corporation, with its principal place of business at 7-2-A2, Hetero Corporate, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, India. "Hetero has a strong established global presence with 36 manufacturing facilities and a robust network of business partners and marketing offices strategically located across the world." Hetero on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. Hetero Labs is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic LCDs throughout the United States.

56. Defendant Hetero USA Inc. ("Hetero USA") is "the US representation of HETERO, a privately owned; researched based global pharmaceutical company." Hetero USA is a Delaware corporation with its principal place of business located at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA is the wholly-owned subsidiary of Hetero. At all times material to this action, Hetero USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded and/or misbranded generic LCDs throughout the United States.

ii. Finished-Dose Level Hetero Entities

57. Defendant Camber Pharmaceuticals, Inc. ("Camber") is a Delaware corporation, with its principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. Camber is the wholly owned subsidiary of Hetero Drugs. At all times material to this action, Camber has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

58. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054, and is a wholly owned subsidiary of Teva. At all times material to this case, Teva USA has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic LCDs in the United States. Teva USA purchased losartan API contaminated with naitrosamines from the Hetero API-level Defendants.

59. Defendant Vivimed Life Sciences Pvt Ltd ("Vivimed") is a foreign corporation, with its principal place of business at Plot No. 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram – 603 110, Tamilnadu, India. Defendant Vivimed purchased LCDs from Defendant Hetero Labs, Ltd. and subsequently sold them to Defendant Heritage Pharmaceuticals, Inc. At all times material to this action, Defendant Vivimed has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

60. Defendant Macleods Pharmaceuticals Ltd. is a foreign corporation, with its principal place of business at Atlanta Arcase, Marol Church Road, Andheri (east), Mumbai – 400059, INDIA.[3] Defendant Macleods Pharmaceuticals Ltd. purchased LCDs from Defendant Hetero and sold these LCDs through its subsidiary, Macleods Pharma USA, Inc. At all times material to this action, Defendant Macleods Pharmaceuticals Ltd. has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

61. Defendant Macleods Pharma USA, Inc. is a Delaware corporation, with its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey

[3] https://www.macleodspharma.com/contact.asp.

08536. Defendant Macleods Pharma USA is a wholly owned subsidiary of Macleods Pharmaceuticals, Ltd. and sold LCDs manufactured by Macleods Pharmaceuticals, Ltd., containing API sourced from Hetero. At all times material to this action, Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

62. Defendant Torrent Private Limited is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Torrent on its own and/or through its subsidiaries regularly conducts business throughout the United States of America and its territories and possessions. At all times material to this case, Torrent has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded LCDs in the United States.

63. Defendant Torrent Pharmaceuticals, Ltd. ("Torrent Pharmaceuticals") is a foreign corporation with its principal place of business at Torrent House, Off. Ashram Road, Ahmedabad - 380009, Gujarat, India, and a United States headquarters at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. Over seventy percent of Torrent Pharmaceuticals is owned by Torrent. Torrent Pharmaceuticals on its own and/or through its subsidiaries regularly conducts business throughout the United States and its territories and possessions. At all times material to this case, Torrent Pharmaceuticals has been engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded LCDs in the United States. Torrent Pharmaceuticals, Ltd. manufactured finished dose LCDs with API purchased from Hetero.

64. Defendant Torrent Pharma, Inc. ("Torrent Pharma") is a Delaware corporation with its principal place of business at 150 Allen Road, Suite 102 Basking Ridge, New Jersey 07920. It is

a wholly-owned subsidiary of Torrent Pharmaceuticals. At all times material to this case, Torrent Pharma has been engaged in the manufacturing, sale, and distribution of LCDs in the United States. Torrent Pharma, Inc. is the United States subsidiary of Defendant Torrent Pharmaceuticals, Ltd. and was responsible for distribution of the LCDs at issue to United States consumers. The LCDs sold and distributed by Torrent Pharma, Inc. contained API sourced from Hetero. Collectively, Torrent Private Limited, Torrent Pharmaceuticals, Ltd., and Torrent Pharma, Inc. shall be referred to as "Torrent."

iii. Repackager and Relabeler Defendants

65. Defendant Legacy Pharmaceutical Packaging, LLC is a Missouri corporation, with its principal place of business at 13333 Lakefront Drive, Earth City, Missouri 63045. Defendant Legacy Pharmaceutical Packaging purchased LCDs from Defendant Camber Pharmaceuticals and subsequently sold them to Defendant Wal-Mart for distribution. Defendant Legacy Pharmaceutical Packaging also purchased and sold product sourced from Torrent, which contained API sourced from Hetero. At all times material to this action, Legacy Pharmaceutical Packaging, LLC has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

66. Defendant H J Harkins Co., Inc., dba Pharma Pac is a California corporation, with its principal place of business at 1400 West Grand Avenue, Suite F, Grover Beach, CA, 93433. Defendant H.J. Harkins Co. Inc. is a repackager for LCDs manufactured by Camber, which contained API from Defendant Hetero Labs.

67. Defendant Golden State Medical Supply, Inc. is a California corporation, with its principal place of business at 5187 Camino Ruiz, Camarillo, California 93012. Defendant Golden State Medical Supply, Inc. purchased LCDs from Defendant Teva Pharmaceuticals USA,

Inc. At all times material to this action, Golden State Medical Supply, Inc. has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

68. Defendant Heritage Pharmaceuticals, Inc. d/b/a/ Avet Pharmaceuticals ("Heritage Pharmaceuticals") is a Delaware corporation, with its principal place of business at One Town Center Boulevard, East Brunswick, New Jersey 08816. Defendant Heritage purchased LCDs from Defendant Vivimed. At all times material to this action, Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

69. Defendant AvKARE, Inc. is a Tennessee corporation, with its principal place of business at 615 N 1st Street, Pulaski, TN 38478-2403.[4] Defendant AvKARE, Inc. sold, repackaged, and/or relabeled LCDs purchased from Macleods Pharma USA, Inc. and Macleods Pharmaceuticals Ltd., which contained API sourced from Hetero. At all times material to this action, Defendant Heritage has been engaged in the manufacturing, sale, and distribution of adulterated, misbranded, and/or unapproved LCDs throughout the United States.

70. Defendant RemedyRepack, Inc. is a Pennsylvania corporation, with its principal place of business at 625 Kolter Drive, Suite 4, Indiana, PA 15701.[5] Defendant RemedyRepack is a repackager for LCDs manufactured by Torrent, with API coming from Hetero.

71. Defendant Preferred Pharmaceuticals, Inc. is a California corporation, with its principal place of business at 1250 North Lakeview Ave., Unit O, Anaheim CA 92807.[6] Preferred

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[4] https://tnbear.tn.gov/Ecommerce/FilingDetail.aspx?CN=037070117200242054095162190238057130083225172225

[5] http://www.remedyrepack.com/RemedySite2/Pages/Home.aspx;

[6] https://businesssearch.sos.ca.gov/CBS/Detail; https://www.manta.com/c/mms62wn/preferred-pharmaceuticals-inc

Pharmaceuticals, Inc. is a repackager for LCDs manufactured by Torrent, which contained API sourced from Hetero.

72. Defendant Major Pharmaceuticals, Inc. is a corporation, with its principal place of business at 17177 North Laurel Park, Suite 233, Livonia, MI 48152. Defendant Major Pharmaceuticals, Inc. distributed LCDs supplied by Torrent, with API manufactured by Hetero.

iv. Pharmacy Defendants

a. CVS Health

73. Defendant CVS Health Corporation ("CVS Health") is a national retail pharmacy chain incorporated in Delaware with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island.

74. As of March 31, 2019, Defendant CVS Health maintained approximately 9,900 retail pharmacy locations across the United States, making it one of the largest in the country. Defendant CVS Health also operates approximately 1,100 walk-in medical clinics and a large pharmacy benefits management service with approximately 94 million plan members.

75. According to its 2018 Annual Report, Defendant CVS Health's "Pharmacy Services" segment "provides a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, mail order pharmacy, specialty pharmacy and infusion services, Medicare Part D services, clinical services, disease management services and medical spend management. The Pharmacy Services segment's clients are primarily employers, insurance companies, unions, government employee groups, health plans, Medicare Part D prescription drug plans ("PDPs"), Medicaid managed care plans, plans offered on public health insurance exchanges and private

health insurance exchanges, other sponsors of health benefit plans and individuals throughout the United States."

76. CVS Health's Pharmacy Services segment generated U.S. sales of approximately $134.1 billion in 2018.

77. CVS Health's Retail/LTC segment is responsible for the sale of prescription drugs and general merchandise. The Retail/LTC segment generated approximately $84 billion in U.S. sales in 2018, with approximately 75% of that attributed to the sale of pharmaceuticals. During 2018 the Retail/LTC segment filled approximately 1.3 billion prescriptions on a 30-day equivalent basis. In December 2018, CVS's share of U.S. retail prescriptions accounted for 26% of the United States retail pharmacy market.

78. In or about 2015, CVS Health acquired all of Target Corporation's pharmacies. "CVS," as defined herein, includes any current or former Target pharmacy.

79. In 2014, CVS Health and wholesaler Cardinal Health, Inc. ("Cardinal") established a joint venture to source and supply generic pharmaceutical products through a generic pharmaceutical sourcing entity named Red Oak Sourcing, LLC ("Red Oak"), of which CVS Health and Cardinal each own fifty percent. Most or all of the valsartan-containing drugs purchased by CVS Health were acquired through this joint venture with Cardinal.

80. Upon information and belief, Defendant CVS Health sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

b. Walgreen Co.

81. Defendant Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015.

82. Upon information and belief, Defendant Walgreens Co. sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

c. Walgreens Boots Alliance, Inc.

83. Walgreens Boots Alliance, Inc. is the parent Corporation of Defendant Walgreen Co.

84. Walgreens Boots Alliance, Inc. is Delaware with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois.

85. Walgreen Co. and Walgreens Boots Alliance, Inc. are collectively referred to within this Complaint as "Walgreens."

86. Walgreens is one of the retail pharmacy chains in the United States, offering retail pharmacy services and locations in all 50 states including the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. As of August 31, 2018, Walgreens operated 9,560 retail pharmacies across the United States, with 78% of the U.S. population living within five 5 miles of a store location. In addition, Walgreens recently purchased an additional 1,932 store locations from rival Rite Aid Corporation, further consolidating the industry. Walgreens' sales amounted to a staggering $98.4 billion in 2018, most of which are generated for prescription sales. Walgreens accounts for nearly 20% of the U.S. market for retail prescription drug sales.

87. Walgreens is one of the largest purchasers of pharmaceuticals in the world, and according to its Form 10-K for 2018, the wholesaler AmerisourceBergen "supplies and distributes a significant of generic and branded pharmaceutical products to the [Walgreens] pharmacies."

88. In or about 2017, Walgreens acquired control of Diplomat Pharmacy. "Walgreens," as defined herein, includes any current or former Diplomat pharmacy. Upon information and belief, Defendant Walgreens sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

d. OptumRx

89. Defendant OptumRx is a Minnesota corporation, with its principal place of business at 2300 Main Street, Irvine, CA 92614.[7]

90. Defendant Optum Rx sold LCDs directly to Plaintiffs.

91. Upon information and belief, Defendant Optum Rx sold thousands of the adulterated and/or misbranded LCDs directly to U.S. consumers such as Plaintiffs.

e. Optum, Inc.

92. Defendant Optum, Inc. is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[8]

93. Upon information and belief, Defendant Optum Rx is a wholly owned subsidiary of Defendant Optum, Inc.

94. Upon information and belief, Defendant Optum Rx, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

f. UnitedHealth Group

95. Defendant UnitedHealth Group is a Minnesota corporation, with its principal place of business at 11000 Optum Circle, Eden Prairie, MN 55344.[9]

96. Upon information and belief, Defendant Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group.

97. Upon information and belief, Defendant United Health Group, together with its corporate affiliates, sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

[7] https://www.optumrx.com/public/information-center/public-contact-us
[8] https://www.optum.com/contact.html
[9] https://www.optum.com/contact.html

g. Wal-Mart, Inc.

98. Defendant Walmart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

99. Upon information and belief, Defendant Wal-Mart, Inc. (including Sam's Club) sold thousands of the adulterated and/or misbranded LCDs to U.S. consumers such as Plaintiffs.

v. Wholesaler Defendants

100. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

101. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

102. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

103. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

a. Cardinal Health, Inc.

104. As mentioned above, Defendant Cardinal Health, Inc. is a corporation, with its principal place of business at 7000 Cardinal Place, Dublin, OH 43017.[10]

b. McKesson Corporation

105. Upon information and belief, Defendant McKesson Corporation is a Delaware corporation with its principal place of business located at 6535 North State Highway 161, Irving, Texas 75039.

c. AmerisourceBergen Corporation

106. Defendant AmerisourceBergen Corp. is a Delaware corporation with its principal place of business located at 1300 Morris Drive, Chesterbrook, PA 19087.

vi. Doe Defendants

107. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of DOES 1 through 100, inclusive, are unknown to Plaintiffs at this time, who therefore sue defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as hereinafter alleged; and that each DOE Defendant is liable to the Plaintiffs for the acts and omissions alleged herein below, and the resulting injuries to Plaintiffs, and damages sustained by the Plaintiffs. Plaintiffs will amend this Complaint to allege the true names and capacities of said DOE Defendants when the same is ascertained.

108. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, each of the DOE Defendants were the agent, servant, employee and/or joint venturer of the other co-defendants and other DOE Defendants, and each of them, and at all said times,

[10] https://www.theharvarddruggroup.com/shop/contact/index

each Defendant and each DOE Defendant was acting in the full course, scope and authority of said agency, service, employment and/or joint venture.

III. JURISDICTION AND VENUE

109. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28U.S.C. § 1332(d), because (a) at least one member of the proposed class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed class consists of more than 100 class members, and (d) none of the exceptions under the subsection apply to this action.

110. This Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1407, and because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

111. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because Defendants reside in this District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

IV. FACTUAL ALLEGATIONS

A. Prescription Drug Reimbursement

112. The pharmaceutical supply chain in the United States consists of four major actors: pharmaceutical manufacturers, wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs").

113. Pharmaceutical manufacturers produce drugs which they distribute to wholesale distributors, who further distribute to retail or mail-order pharmacies. Pharmacies dispense the prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality and utilization management screens by PBMs.

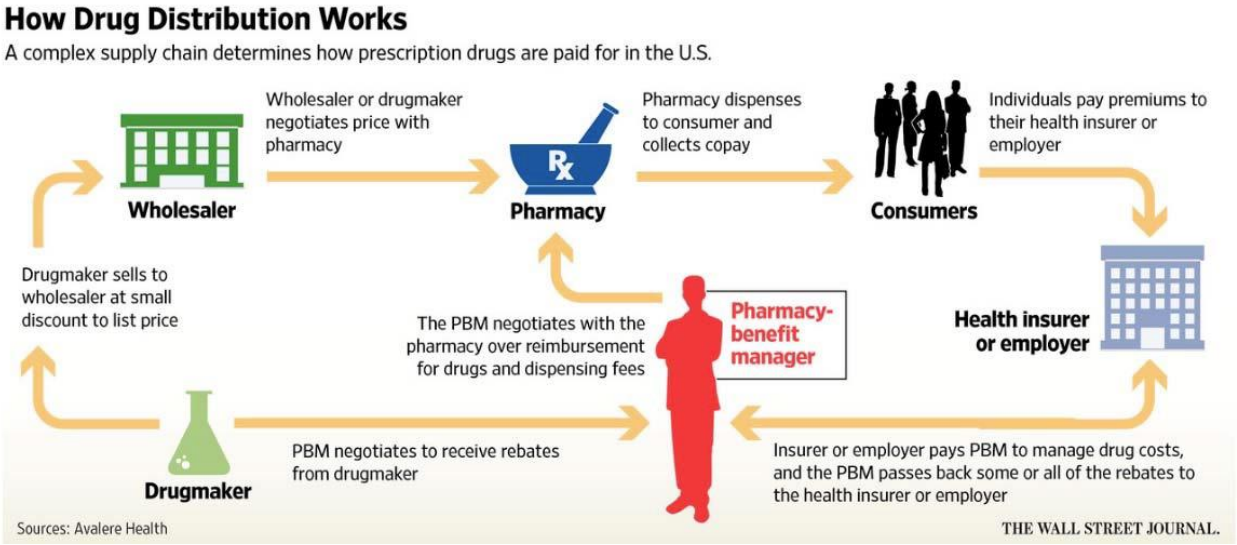
114. TPPs contract with and pay PBMs to administer their drug programs. PBMs, acting as agents for the TPPs, are tasked with developing drug formularies (the list of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. TPPs pay PBMs to control prescription drug costs. In some instances, PBMs are responsible for placing generic drugs, such as LCDs, on the TPPs' formularies.

115. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are bioequivalent or otherwise the same as their RLD counterparts. As is the case with all generic drugs, TPPs seek to include the lowest cost generic drugs possible in their formularies. This is only made possible because of the manufacturers' and distributors' representations that these generic drugs, such as the Defendants' LCDs, comply with their respective ANDAs, which state that the generic drugs are bioequivalent to their respective branded drug. Thus, the TPPs permitted the LCDs to be included on their formularies based on the Defendants' misrepresentations that their LCDs were

bioequivalent to brand-named Diovan, complied with all cGMPs, and were safe for consumption.

116. The formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the co-payment, and the higher likelihood that the drug will be purchased by plan beneficiaries in lieu of a more expensive alternative, and vice versa. As such, higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to aid prescribers' adherence to the formulary.

117. The following chart, published by the Wall Street Journal, broadly illustrates the pharmaceutical supply chain:[11]



118. When a patient presents his/her prescription at a pharmacy, the drug's placement on the TPP's formulary will determine the amount of the patient's co-payment. Once the

[11] Joseph Walker, Drugmakers Point Finger at Middlemen for Rising Drug Prices, WALL ST. J. (Oct. 3, 2016), available at https://www.wsj.com/articles/drugmakers-point-finger-at-middlemen-for-rising-drug-prices-1475443336 (last accessed June 11, 2019).

patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then cumulate those individual reimbursements and present them to TPPs for payment.

B. Generic Drugs Must Be Chemically The Same As Branded Drug Equivalents

119. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that **a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.** In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[12]

120. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA, which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient(s) in the generic medicine is/are the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

[12] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last accessed June 5, 2019) (emphasis in original).

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.[13]

121. The drugs ingested by Plaintiffs were approved by the FDA, based upon Defendants' representations that they met the above criteria.

122. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.[14]

123. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they are also supposed to have the same risks and benefits.[15]

C. Adulterated or Misbranded Drugs

124. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law.[16]

125. The introduction into commerce of any misbranded or adulterated or misbranded drug is similarly prohibited.[17]

126. Similarly, the receipt in interstate commerce of any adulterated or misbranded or misbranded drug is also unlawful.[18]

127. Among the ways a drug may be adulterated and/or misbranded are:

[13] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm.
[14] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[15] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.
[16] 21 U.S.C. § 331(g).
[17] 21 U.S.C. § 331(a).
[18] 21 U.S.C. § 331(c).

a. "if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;"[19]

b. "if . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;"[20]

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth in such compendium. …"[21]

d. "If . . . any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[22]

128. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[23]

b. "If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and

[19] 21 U.S.C. § 351(a)(2)(A).
[20] 21 U.S.C. § 351(a)(2)(B).
[21] 21 U.S.C. § 351(b).
[22] 21 U.S.C. § 351(d).
[23] 21 U.S.C. § 352(a)(1).

understood by the ordinary individual under customary conditions of purchase and use."[24]

c. If the labeling does not contain, among other things, "the proportion of each active ingredient…"[25]

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. …"[26]

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[27]

f. "if it is an imitation of another drug;"[28]

g. "if it is offered for sale under the name of another drug."[29]

h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[30]

i. If the drug is advertised incorrectly in any manner;[31] or

[24] 21 U.S.C. § 352(c).
[25] 21 U.S.C. § 352(e)(1)(A)(ii)
[26] 21 U.S.C. § 352(f).
[27] 21 U.S.C. § 352(g).
[28] 21 U.S.C. § 352(i)(2).
[29] 21 U.S.C. § 352(i)(3).
[30] 21 U.S.C. § 352(j).
[31] 21 U.S.C. § 352(n).

j. If the drug's "packaging or labeling is in violation of an applicable regulation…"[32]

129. As articulated in this Complaint, Defendants' unapproved LCDs were adulterated and/or misbranded in violation of all of the above-cited reasons.

D. Losartan Medications Are Recalled By The FDA Due To Presence Of Nitrosamines

130. The medication in question in this case is a drug that Defendants marketed and sold under the name "losartan."

131. Losartan is a generic version of the brand-name medication, Cozaar, and losartan with hydrochlorothiazide (HCTZ) is a generic version of Hyzaar.

132. Losartan is used to treat high blood pressure and heart failure, and to improve a patient's chances of living longer after a heart attack.

133. Losartan is classified as an angiotensin receptor blocker (ARB) that is selective for the type II angiotensin receptor. It works by relaxing blood vessels so that blood can flow more easily, thereby lowering blood pressure.

134. Losartan potassium can be sold by itself or as a single pill which combines losartan with HCTZ.

135. The drug binds to angiotensin type II receptors (AT1), working as an antagonist.

136. The patents for Cozaar and Hyzaar expired in August 2009.[33]

137. Shortly after the patents for Cozaar and Hyzaar expired, the FDA began to approve generic versions of the drugs.

[32] 21 U.S.C. § 352(p).
[33] https://www.fiercepharma.com/special-report/cozaar-hyzaar-big-patent-expirations-of-2010.

138. Due to manufacturing defects in generic formulations of losartan, the LCDs became contaminated with nitrosamines, specifically NDEA and NMBA.

1. NDEA

139. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is very soluble in water.[34]

140. NDEA is classified as a probable human carcinogen and a known animal carcinogen.[35]

141. NDEA is an even more potent carcinogen than NDMA, which was the nitrosamine contaminant found in valsartan-containing medications.[36]

142. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

143. Hematological effects were also reported in animal studies.[37]

144. Tests conducted on rats, mice, and hamsters demonstrated that NDEA has high to extreme toxicity from oral exposure.[38]

145. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."[39]

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[34] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[35] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68448a-eng.php; *see also* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620499.htm.
[36] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm
[37] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[38] https://www.epa.gov/sites/production/files/2016-09/documents/n-nitrosodimethylamine.pdf.
[39] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf (emphasis in original).

146. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."[40]

147. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.[41]

2. NMBA

148. NMBA is another nitrosamineidentified in sartan medications by the FDA.[42]

149. Due to its structural similarities to NDMA and NDEA, NMBA is considered by international regulators such as the World health Organization to have a similar toxicological profile to NDMA and NDEA.[43]

150. When NMBA was first discussed in an FDA press release, FDA noted, "We are deeply concerned about the presence of a third nitrosamine impurity in certain ARB medications, but it's important to underscore that, based on the FDA's initial evaluation, the increased risk of cancer to patients with NMBA exposure appears to be the same for NDMA exposure but less than the risk from NDEA exposure. That said, any presence of such impurities in drug products is not acceptable."[44]

[40] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[41] https://nj.gov/health/eoh/rtkweb/documents/fs/1404.pdf.
[42] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[43] https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en/.
[44] https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine.

151. Thus, the FDA set interim consumption limits of NMBA at 96 nanograms per day, which is the same interim level set for daily consumption of NDMA.[45]

152. Like NDMA and NDEA, NMBA has been a chemical of choice used in animal studies to induce cancer in animal study subjects, because it is known to induce cancer.[46]

153. Testing and evaluation is ongoing of LCDs manufactured, distributed, or sold by Defendants. Besides these nitrosamines, ongoing investigation suggests other impurities, such as NMBA, may exist as well in the LCDs at issue.

3. U.S. Losartan Recalls

154. Predating the losartan recalls were a wave of valsartan recalls. Valsartan is another ARB medication, in the same family of medications as losartan.

155. On July 13, 2018, the Food and Drug Administration announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Zhejiang Huahai Pharmaceuticals."[47] FDA further noted that the valsartan-containing drugs being recalled "does not meet our safety standards."[48]

156. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow.

157. On August 9, 2018, FDA announced that it was expending the recall to include valsartan-containing products manufactured by another API manufacturers, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained

[45] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[46] https://pubmed.ncbi.nlm.nih.gov/3180095/.
[47] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
[48] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.

unacceptable levels of NDMA.[49] FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."[50]

158. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall notices also stated that the recalls related to unexpired valsartan-containing products.[51]

159. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."[52]

160. The first losartan recall occurred on November 9, 2018, wherein Sandoz, Inc. voluntarily recalled one lot of losartan due to presence of NDEA.[53]

161. In December of 2018 Torrent recalled some of its of losartan-containing drugs due to presence of NDEA.[54] Torrent expanded its recall of losartan-containing drugs in January, March, April and September of 2019. Defendant Torrent Pharmaceuticals purchased its API

[49] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[50] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[51] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[52] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm.
[53] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-nationwide-recall-one-lot-losartan-potassium-and-hydrochlorothiazide-due (last visited 1/11/20).
[54] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-tablets-usp (last visited 1/11/20).

from Defendant Hetero Labs. Defendants AvKare, RemedyRepack, Inc. Preferred Pharmaceuticals, Inc. and Legacy Pharmaceutical Packaging, LLC are a few of the labelers and repackagers who get their losartan-containing drugs from Torrent.

162. In January 2019, Defendant Torrent expanded its recall to include several additional lots of losartan due to presence of NDEA.[55]

163. On March 1, 2019, Torrent expanded its losartan recall again due to the presence of NMBA.[56]

164. On April 18, 2019, Torrent expanded its recall to include an additional 36 lots of losartan due to the presence of NMBA.[57] Torrent's NMBA recall was later expanded on September 23, 2019.[58]

165. On April 18, 2019, approximately four months after the initial recall stemming from the same overseas API supplier, Torrent expanded its recall to add over a million[59] additional bottles of losartan-containing medication to the recall due to the presence of NMBA.[60]

[55] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-tablets-usp (last visited 1/11/20).
[56] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-0 (last visited 1/11/21).
[57] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium (last visited 1/11/21).
[58] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-0 (last visited 1/11/21).
[59] https://www.fiercepharma.com/manufacturing/torrent-recalls-more-than-1m-bottles-tainted-blood-pressure-med (last visited 5/7/19).
[60] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium (last visited 5/7/19).

166. In February 2019, the Macleods Defendants recalled certain losartan-containing drugs with API also purchased from Defendant Hetero Labs, Ltd. due to the presence of NDEA.[61] The Macleods Defendants later substantially expanded the recall in June 2019 due to the presence of NMBA.[62]

167. On February 28, 2019, Defendant Hetero and its distributor, Camber, issued a recall for many of its losartan-containing drugs due to presence of NMBA.[63] Defendant Camber supplied losartan-containing drugs to both Legacy Pharmaceutical Packaging, LLC and HJ Harkins Co. d/b/a Pharm Pac.

168. On March 15, 2019, Defendant Legacy Pharmaceutical Packaging, LLC announced a recall of certain lots of losartan due to presence of NMBA.[64] Legacy stated that the "recall was prompted due to Torrent Pharmaceuticals LTD issuing a Voluntary Nationwide Recall of Losartan Tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer)."[65]

169. On March 19, 2019, Legacy announced a recall of 40 repackaged lots of losartan due to the presence of NMBA, which was "prompted due to Camber Pharmaceuticals, Inc.

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[61] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/macleods-pharmaceuticals-limited-issues-voluntary-nationwide-consumer-level-recall-one-lot-blm-715a
[62] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/macleods-pharmaceutical-limited-issues-voluntary-nationwide-consumer-level-recall-losartan-potassium (last visited 1/11/21)
[63] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-losartan-potassium-tablets-usp-25-mg (last visited 1/11/21).
[64] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-issues-voluntary-nationwide-recall-losartan-potassium-tablets-1 (last visited 1/11/21).
[65] *Id.*

issuing a Voluntary Nationwide Recall of Losartan Tablets, USP, due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, (API manufacturer)." Legacy expanded the recall several times.[66] [67] [68]

170. On April 26, 2019, Defendant Teva Pharmaceuticals USA, Inc. initiated a recall of 35 lots of losartan due to the presence of NMBA.[69] "The lots were sold exclusively to Golden State Medical Supply of Camarillo, California. Golden State Medical Supply packages this bulk product under its own label and distributes in retail bottles of 30, 90, and 1000 tablets."[70] The API in Teva's products was purchased from Defendant Hetero Labs, Ltd.

171. On June 10, 2019, Defendant Teva Pharmaceuticals USA, Inc. expanded its recall to include six additional lots of losartan due to presence of NMBA.[71] These lots were also sold to Defendant Golden State Medical Supply.

[66] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-issues-voluntary-nationwide-recall-losartan-potassium-tablets (last visited 1/11/21).
[67] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-issues-voluntary-nationwide-recall-losartan-potassium-tablets-0 (last visited 1/11/21).
[68] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-expands-voluntary-nationwide-recall-losartan-potassium-tablets (last visited 1/11/21).
[69] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-and-100-mg (last visited 1/11/21).
[70] *Id.*
[71] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-expands-voluntary-nationwide-recall-losartan-potassium-50-mg-and-100-mg (last visited 1/11/21).

172. On May 3, 2019, Defendant Vivimed Life Sciences Pvt Ltd announced a recall of 19 lots of losartan due to the presence of NMBA.[72] Vivimed's losartan was distributed to Defendant Heritage Pharmaceuticals Inc.[73] Defendant Vivimed's API was also sourced from Hetero Labs, Ltd.

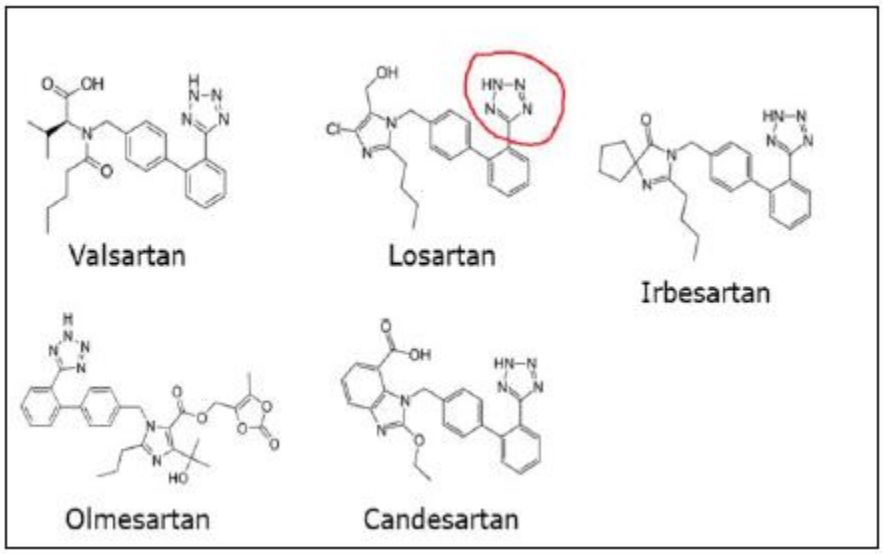
173. On October 8, 2019, FDA sent a Warning Letter to Torrent Pharmaceuticals, Limited, citing the company with numerous "significant" violations of cGMPs relating to their losartan-containing drugs.[74] Specifically, FDA noted that Torrent failed to follow its process validation protocol and after multiple batches of API failed tests, Torrent developed alternate protocols to "justify commercial use of the alternate API, even though [Torrent] had data demonstrating [its] process was not capable of producing quality material using the new alternate API."[75]

E. Formation Of Nitrosamines In The LCDs

174. The nitrosamines at issue in this case are considered genotoxic compounds, as they all contain nitroso groups, which are gene-mutating groups.[76]

[72] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vivimed-life-sciences-pvt-ltd-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-50-mg-and (last visited 1/11/21).
[73] *Id.*
[74] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019.
[75] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019.
[76] https://www.pharmaceuticalonline.com/doc/nitroso-impurities-in-valsartan-how-did-we-miss-them-0001.

175. N-nitrosamines are formed at the tetrazole ring present in ARB medications, including valsartan, losartan, and irbesartan. The tetrazole ring is visually depicted in the following diagram[77]:

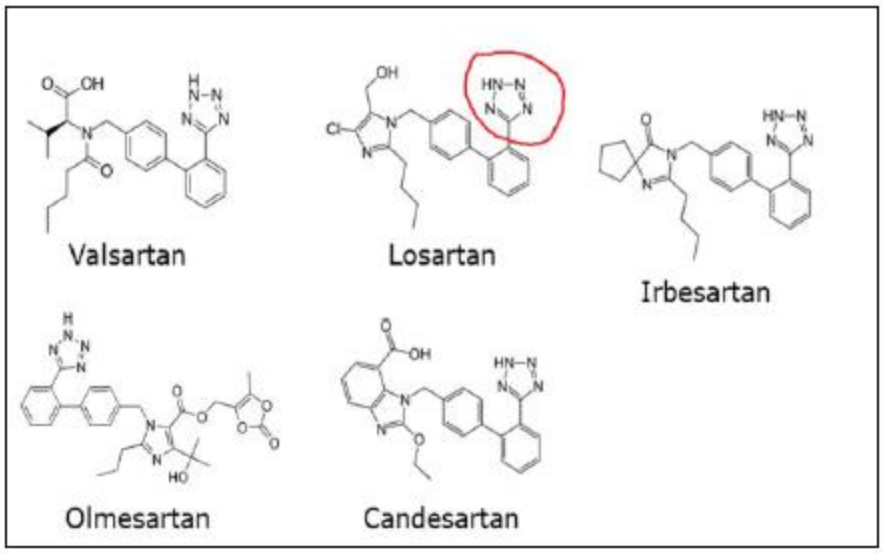


176. N-nitrosamines are formed as part of the synthetic process or through introduction of N-nitrosamines through use of recovered solvents.

177. As to the synthetic process, "formation of N-nitrosamines is only possible in the presence of a secondary or tertiary amine and nitrite, usually under acidic reaction conditions."[78]

178. NDMA is derived from the decomposition of dimethylformamide (DMF) at high temperatures to dimethylamine (DMA). DMA acts as the secondary amine leading to formation of NDMA, as shown in the following diagram:

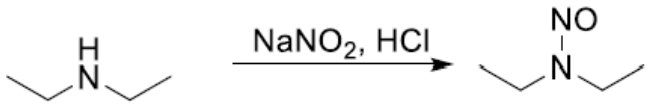
[77] Committee for Medicinal Products for Human Use, Assessment Report Article 31 Angiotensin-II-Receptor Antagonists (sartans) Containing a Tetrazole Group, at 3-4 (European Medicines Agency 2019).
[78] *Id.* at 5.



179. DMA may also be present as an impurity in DMF as it is a precursor in the industrial DMF synthetic process, which can then lead to formation of NDMA in the ARB drugs. DMA "may also be a degradant formed during storage of the solvent, potentially present as the formate salt."[79]

180. NDEA is "generated from diethylamine (DEA) by analogy to the formation of NDMA from DMA," as depicted in the following diagram[80]:

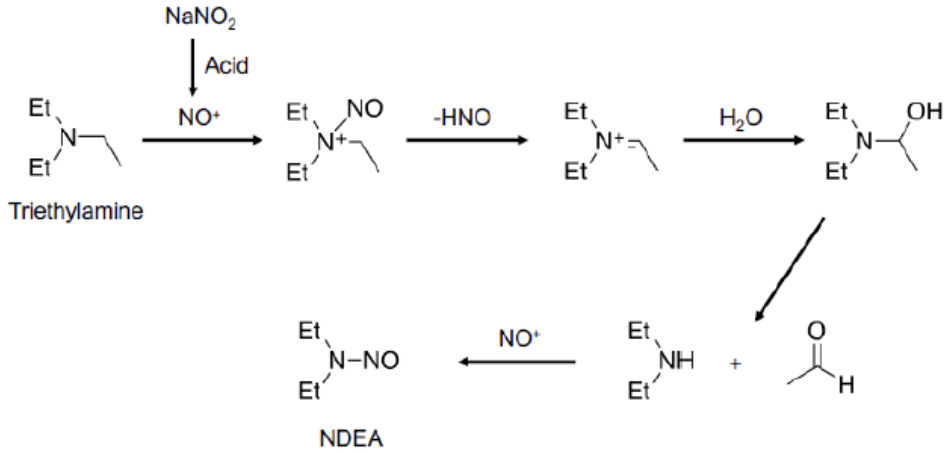
Fig.: 3 General reaction scheme for formation of NDEA from diethylamine



[79] *Id.*
[80] *Id.*

181. Alternatively, "direct nitrosation of TEA may occur via a nitrosoiminium ion, resulting in the generation of an aldehyde and a secondary amine, which reacts with further nitrous acid to form a nitrosamine."[81]

Fig. 4: Nitrosative cleavage of TEA to DEA followed by nitrosation to NDEA



182. Upon information and belief, the nitrosamine contamination in the LCDs is also the result of the API Manufacturer Defendants utilizing recycled or recovered solvents during the manufacture of the Active Pharmaceutical Ingredient ("API").

183. NMBA is "formed during the synthesis of losartan while using sodium nitrite and N-methylpyrrolidone."[82]

184. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs at least as far back as 2005.[83]

F. The Drugs Ingested By Plaintiffs Were Not Losartan, But New, Unapproved LCDs Not Of The Same Quality

185. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure,

[81] *Id.* at 6.
[82] *Id.* at 25.
[83] http://www.pharma.gally.ch/UserFiles/File/proofs%20of%20article.pdf.

> mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients.[84]

186. 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."[85]

187. NDEA and NMBA both have the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDMA and NDEA are, by definition, active ingredients in a drug.

188. FDA further requires that whenever a new active ingredient is added to a drug, the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.[86]

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[84] https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm511482.htm#drug.

[85] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3. (last visited 1/11/21).

[86] See 21 C.F.R. § 310.3(h).

189. This new and unapproved drug with additional active ingredients (such as nitrosamines in the subject LCDs) cannot be required to have the same label as the brand-name drug, as the two products are no longer the same.

190. At the very least and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are adulterated or misbranded under federal law, and the sale or introduction into commerce of adulterated or misbranded drugs is illegal.[87]

191. Because the LCDs ingested by Plaintiffs were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

192. The inclusion of additional active ingredients (NDEA and NMBA), and potentially other deviations from Defendants' ANDA approvals rendered Defendants' LCDs of a lesser quality than FDA-approved generic losartan.

193. Plaintiffs reference federal law in this Complaint not in any attempt to enforce it, but to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

G. Defendants Made False Statements In The Labeling Of Their LCDs

194. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[88] and conform to requirements governing the appearance of the label.[89]

[87] See generally https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false (last accessed June 6, 2019).
[88] 21 C.F.R. § 201.5.
[89] 21 C.F.R. § 801.15.

195. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[90] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

196. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[91]

197. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[92]

198. Because NDEA and/or NMBA were not disclosed by Defendants as ingredients in the LCDs ingested by Plaintiffs, the subject drugs were misbranded.

199. In addition, by referring to their drugs as "losartan" or "amlodipine and losartan," Defendants were making false statements regarding their LCDs.

200. It is unlawful to introduce a misbranded drug into interstate commerce.[93] Thus, the LCDs ingested by individual Plaintiffs were unlawfully distributed and sold.

H. <u>The Generic Drug Supply Chain In The United States</u>

201. The generic drug supply chain from manufacturer to end consumer involves several groups of actors and links.

202. At the top of the supply chain are generic drug manufacturers (and whomever they contract with to manufacture components of pharmaceuticals including, for example, the active pharmaceutical ingredient manufacturer ("API")). Generic drug manufacturers may sell to

[90] Id. 65 Fed. Reg. 14286 (March 16, 2000).
[91] *U.S. v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[92] 21 C.F.R. § 201.6; 201.10.
[93] 21 U.S.C. § 331(a).

other manufacturers or to so-called repackagers or labelers who sell a particular generic drug formulation.

203. Wholesalers in turn purchase bulk generic drug product from the generic manufacturers and/or labelers and repackager entities. The wholesaler market is extremely concentrated, with three entities holding about 92% of the wholesaler market: Cardinal Health, Inc.; McKesson Corporation; and Amerisource Bergen Corporation.

204. Wholesalers sell the generic drug products they acquire to retail pharmacies, who sell them to patients with prescriptions in need of fulfillment. The retail pharmacy market is also dominated by several major players.

I. Background On Current Good Manufacturing Practices ("cGMPs")

205. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

206. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

207. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F);

packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

208. Any drug not manufactured in accordance with cGMPs is deemed "adulterated and/or misbranded" or "misbranded" and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

209. Per federal law, cGMPs include "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j). Accordingly, it is a cGMP violation for a manufacturer to contract out prescription drug manufacturing without sufficiently ensuring continuing quality of the subcontractors' operations.

210. FDA regulations require a "quality control unit" to independently test drug product manufactured by another company on contract:

> There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. 21 C.F.R. § 211.22(a).

211. Indeed, FDA regulations require a drug manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

212. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

213. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

J. <u>The Generic Drug Approval Framework</u>

214. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

215. The stated purpose of Hatch-Waxman is to strike a balance between rewarding genuine innovation and drug discovery by affording longer periods of brand drug marketing exclusivity while at the same time encouraging generic patent challenges and streamlining generic drug competition so that consumers gain the benefit of generic drugs at lower prices as quickly as possible.

216. Brand drug companies submitting a New Drug Application ("NDA") are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 *et seq.*

217. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug ("RLD"). Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

1. *ANDA Applications Must Demonstrate Bioequivalence*

218. The bioequivalence basis for ANDA approval is premised on the generally accepted proposition that equivalence of pharmacokinetic profiles of two drug products is evidence of therapeutic equivalence. In other words, if (1) the RLD is proven to be safe and effective for the approved indication through well-designed clinical studies accepted by the FDA, and (2) the generic company has shown that its ANDA product is bioequivalent to the RLD, then (3) the generic ANDA product must be safe and effective for the same approved indication as the RLD.

219. As part of its showing of bioequivalence pursuant to 21 C.F.R. § 314.50(d), the ANDA must also contain specific information establishing the drug's stability, including:

- a full description of the drug's substance, including its physical and chemical characteristics and stability; and
- the specifications necessary to ensure the identity strength, quality and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability.

220. Generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," *id.* at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. *Id.* at (A)(vi); *see also* § 355(b)(1)(C).

221. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

2. *ANDA Applications Must Provide Information About the Manufacturing Plants and Processes*

222. The ANDA application must also include information about the manufacturing facilities of the product, including the name and full address of the facilities, contact information for an agent of the facilities, and the function and responsibility of the facilities.

223. The ANDA application must include a description of the manufacturing process and facility and the manufacturing process flow chart showing that there are adequate controls to ensure the reliability of the process.

224. Furthermore, the ANDA application must contain information pertaining to the manufacturing facility's validation process which ensures that the manufacturing process produces a dosage that meets product specifications.

3. *ANDA Applications Must Comply with cGMPs*

225. Additionally, ANDA applications must include certain representations pertaining to compliance with cGMPS.

226. The ANDA application is required to contain cGMP certifications for both the ANDA applicant itself, and also the drug product manufacturer (if they are different entities).

4. *ANDA Approval is Contingent upon Continuing Compliance with ANDA Representations of Sameness*

227. Upon granting final approval for a generic drug, the FDA will typically state that the generic drug is "therapeutically equivalent" to the branded drug. The FDA codes generic drugs as "A/B rated" to the RLD[94] branded drug. Pharmacists, physicians, and patients can expect such generic drugs to be therapeutically interchangeable with the RLD, and generic manufacturers expressly warrant as much through the inclusion of the same labeling as the RLD delivered to consumers in each prescription of its generic products. Further, by simply marketing generic drugs pursuant to the brand-name drug's label under the generic name (e.g., losartan potassium or losartan potassium HCTZ), generic manufacturers impliedly warrant that the generic drug is therapeutically equivalent to the brand-name drug.

228. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new and unapproved drug.

229. If a generic drug manufacturer ceases to manufacture a drug that meets all terms of its ANDA approval, or in other words, when the drug is not the same as its corresponding

[94] The FDA's Drug Glossary defines an RLD as follows: "A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart."

brand-name drug, the generic manufacturer may no longer rely on the brand-name drug's labeling.

230. According to the FDA, there are at least twenty one ANDAs approved for generic Cozaar, sixteen for generic Hyzaar.

a. Starting As Early As 2007, Defendants Were Actively Violating cGMPs In Their Foreign Manufacturing Facilities

231. For some time, Defendants have known that generic losartan drugs manufactured overseas were found or suspected to be less safe and effective than their branded equivalents or domestically-made generics due to their grossly inadequate manufacturing processes, procedures and compliance with cGMPs.

232. Defendants' foreign manufacturing operations were no exception to this.

233. Defendant Hetero maintains six API manufacturing facilities in India, which have been approved by the FDA to produce active ingredients for drugs being sold and marketed in the United States.

234. Hetero has a history of deviations from FDA's cGMP standards.

235. In December of 2016, during an inspection of an oral solid dose drug product manufacturing facility, the FDA observed, through closed circuit TV surveillance, that Hetero Quality Assurance technicians and "other individuals" were recorded destroying and altering records pertaining to commercial batch manufacturing immediately before the FDA's onsite regulatory inspection. According to a scathing letter, the FDA noted that the following occurred:

a. Hetero employees brought in a document shredder into the "DOCUMENTS STORAGE AREA" four days prior to the FDA inspection;

b. The FDA observed extensive shredding of what appeared to be "controlled documents" as well as "extensive signing of documents" by Quality Assurance technicians. The FDA

noted that the documents were of a color consistent with batch packaging records and batch manufacturing record. Hetero failed to maintain documentation of what had been shredded;

c. One day prior to the FDA inspection a Hetero contract employee in the Quality Assurance division removed documents from the shredder and placed them in his pocket; and

d. At 1:13am the morning the FDA inspectors were set to arrive at Hetero for their regulatory inspections, individuals were seen shredding documents.

236. In addition to the documented destruction of these manufacturing records, the FDA further observed that production and control records were not prepared for each batch of drug product produced and did not include complete information relating to the production and control of each batch.

237. Additionally, data derived from Hetero's programmable logic controller for compression machines was inconsistent with batch records and validation reports that were submitted to the FDA in support of applications to manufacture and market drugs in the United States.

238. Hetero also failed to include findings of any investigations and follow-up that occurred as a result of investigations into complaints about their drugs.

239. During the December 2016 inspection, equipment at Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero drug products.

240. During the December 2016 visit, FDA inspectors found that "accuracy, sensitivity and reproducibility of test methods" were not established and documented.

241. In an August 15, 2017, warning letter, the FDA strongly recommended that Hetero engage "a consultant, qualified as set forth in 21 CFR 211.34" to assist Hetero Labs in meeting cGMP requirements, but that, ultimately, "executive management remains responsible for fully resolving all deficiencies and ensuring ongoing cGMP compliance."

242. In February of 2018, FDA investigators discovered other manufacturing flaws at an API Manufacturing facility.

243. For example, the FDA found that there was a "failure" by Hetero to "thoroughly review any unexplained discrepancy and failure of a batch or any of its components to meet any of its specifications," whether or not the batch had been already distributed.

244. The FDA investigators further found during that February 2018 inspection that Hetero employees who were engaged in the processing, holding and testing of a drug product lacked the training and experience required to perform their assigned functions. Indeed, in a walk-through with FDA investigators, several quality-control personnel could not explain their assigned functions and processes after "repeated opportunities" to do so.

245. Additionally, FDA investigators concluded that there was "no assurance" that equipment used in API production was being maintained and/or kept under proper conditions for manufacturing operations "to prevent the contamination of the products handled and/or processed in the equipment." Likewise, equipment at the Hetero was found to have not been cleaned and maintained at appropriate intervals to "prevent contamination that would alter the safety, identity, strength, quality and purity" of Hetero's drug products.

246. After the recalls of Hetero's valsartan-containing drugs, FDA Laboratory Analysis testing would later reveal that valsartan 320mg API manufactured by Hetero contained NDMA levels in excess of the FDA's interim limits[95] of 96 ng/day or 0.3 ppm.[96]

247. Subsequently, five different finished dose manufacturers issued recalls of LCDs containing API manufactured from Hetero Labs. These recall notices stated that the LCDs were being recalled because they contained "unacceptable" levels of nitrosamines which exceeded the FDA's set interim limits for NDMA, NDEA, and NMBA.[97]

K. Defendants Had Actual And/or Constructive Notice of NDEA And/Or NMBA Contamination Of Their Adulterated, Misbranded, And/Or Unapproved LCDs

248. The FDA has noted in connection with the LCD recalls that NDEA "has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."[98]

249. The FDA has further noted, in connection with the LCD recalls, that NMBA "is a potential human carcinogen."[99]

250. As alleged above, the LCDs manufactured by the API and Finished Dose Manufacturer defendants were found to contain dangerously high levels of nitrosamines, including NDEA and NMBA.

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[95] To be clear, Hetero's valsartan products should not contain any NDMA.
[96] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products; *see also* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[97] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.
[98] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-tablets-usp (last visited 1/12/21).
[99] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-issues-voluntary-nationwide-recall-losartan-potassium-tablets-1 (last visited 1/12/21).

251. NDEA and NMBA are not FDA-approved ingredients for brand-name Cozaar, Tozaar, and Tozam.

252. Moreover, none of Defendants' LCDs identify NDEA, NMBA, or other nitrosamines as an ingredient on the products' labels or elsewhere. This is because these nitrosamines are probable human carcinogens and are not approved to be included in losartan API or finished-dose products.

253. If Defendants had not routinely disregarded the FDA's cGMPs, including those discussed throughout this Complaint and the FDA's investigation reports and warning letter, and deliberately manipulated and disregarded sampling data suggestive of impurities, or had fulfilled their quality assurance obligations, Defendants would have identified the presence of these nitrosamine contaminants almost immediately.

254. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products[.]" Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c).

255. And as shown above, Defendants' own quality control units are and were responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by each API manufacturer.

256. If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' LCDs would have been discovered in 2012 (or perhaps earlier for other API manufacturers). Defendants were thus on (at

minimum) constructive notice that their LCDs were adulterated and/or misbranded as early as 2012.

L. Defendants' Warranties and Fraudulent and Deceptive Statements to Consumers Regarding Their Generic LCDs

257. Each Defendant made and breached express and implied warranties and also made affirmative misrepresentations and omissions to consumers about their adulterated and/or misbranded LCDs.

1. *Warranties Common To All Manufacturer Defendants*

258. The FDA maintains a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly referred to as the Orange Book.[100] The Orange Book is a public document; Defendants sought and received the inclusion of their LCD products in the Orange Book upon approval of their ANDAs. In securing FDA approval to market generic LCDs in the United States as an Orange Book-listed drug, Defendants were required to demonstrate that their generic LCDs were bioequivalent to their RLDs.

259. Therapeutic equivalence for purposes of generic substitution is a continuing obligation on the part of the manufacturer. For example, according to the FDA's Orange Book, therapeutic equivalence depends in part on the manufacturer's continued compliance with cGMPs.

260. Each Defendant's LCD(s) is/are accompanied by an FDA-approved label. By presenting consumers with an FDA-approved LCD label, Defendants, as generic manufacturers,

[100] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) SHORT DESCRIPTION, at https://www.fda.gov/drugs/informationondrugs/approveddrugs/approveddrugproductswiththerapeuticequivalenceevaluationsorangebook/default.htm (last accessed June 5, 2019).

made representations and express or implied warranties to consumers and TPPs of the "sameness" of their products to the LCD's RLD, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded or misbranded.

261. By introducing their respective LCDs into the United States market as a therapeutic equivalent to their RLDs and with the FDA-approved label that is the same as that of the RLDs, Defendants represent and warrant to end users and TPPs that their LCDs are in fact the same as and are therapeutically interchangeable with their RLDs. Much of the generic drugs supply chain, including the most critical components of that supply chain (end-user patients and reimbursing TPPs) rely on these representations and warranties.

262. In addition, each Defendant affirmatively misrepresented and warranted to consumers and TPPs through their websites, brochures, and other marketing or informational materials that their LCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

263. The presence of nitrosamines in Defendants' LCDs: (1) renders Defendants' LCDs non-bioequivalent (*i.e.*, not the same) to their RLDs and thus non-therapeutically interchangeable with them, thus breaching Defendants' express warranties of sameness; (2) was the result of gross deviations from cGMPs rendering Defendants' LCDs non-therapeutically equivalent to their RLDs, thus breaching Defendants' express warranties of sameness; and (3) results in Defendants' LCDs containing an ingredient that is not also contained in their RLDs, also breaching Defendants' express warranty of sameness (and express warranty that the products contained the ingredients listed on each Defendant's FDA-approved label). Each

Defendant willfully, recklessly, or negligently failed to ensure their LCDs' labels and other advertising or marketing statements accurately conveyed information about their products.

264. The presence of nitrosamines in Defendants' LCDs and Defendants' serial and willful failures to comply with cGMPs and other shortcomings in Defendants' generic drug manufacturing processes have resulted in Defendants' LCDs being adulterated and/or misbranded compared to Defendants' representations and warranties.

265. At all relevant times, Defendants have also impliedly warranted that their LCDs were merchantable and fit for their ordinary purposes.

266. Naturally, due to their status as probable human carcinogens as listed by both the IARC and the U.S. EPA, NDEA and NMBA are not FDA-approved ingredients in the LCDs. The presence of NDEA, NMBA and other similar nitrosamines or impurities in Defendants' LCDs means that Defendants have violated implied warranties to Plaintiffs and Class Members. The presence of NDEA or NMBA in Defendants' LCDs results in Defendants' LCDs being non-merchantable and not fit for its ordinary purposes (i.e., as a therapeutically interchangeable generic version of their RLDs), breaching Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

267. For these and other reasons, Defendants' LCDs are therefore adulterated, misbranded, and/or unapproved, and it was illegal for Defendants' to have introduced such LCDs in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

268. Adulterated, misbranded, and/or unapproved LCDs contaminated with cancer-causing compounds are essentially worthless. No reasonable consumer (including Plaintiffs) would purchase (or reimburse for) these nitrosamine-laden LCDs. Nor could they, as an adulterated, misbranded, and/or unapproved LCD cannot even be legally sold or purchased

within the United States. At a minimum, adulterated, misbranded, and/or unapproved LCDs were worth less than their non-contaminated equivalents. Further, adulterated, misbranded, and/or unapproved LCDs do not possess the same safety and efficacy profile as their branded equivalents. As such, the LCDs were not what they were supposed to be.

269. Moreover, every consumer (and every TPP's insured) who purchased and ingested a LCD, including Plaintiffs (or Plaintiffs' insureds), has been exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and subcellular levels, and may give rise to future potential health consequences.

270. The recalls were meant to quickly remove unsafe products from the market. While FDA advised patients to continue taking LCDs, it only did so because of the risks associated with untreated high blood pressure.

271. In response to the recall, pharmacies and health care providers throughout the United States contacted affected patients to advise them of the recall and to recommend that they contact their doctors to request a replacement or an alternative treatment option.

272. Because of the seriousness of the impurity—unsafe levels of a carcinogen— all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. LCDs had no use and were discarded.

2. *Hetero Defendants' Warranties*

273. In touting itself, Hetero claims that it has "over 36 advanced manufacturing facilities strategically located across the world – including India, USA, China, Russia, Egypt, Mexico and Indonesia. Approved by stringent global regulatory authorities, Hetero facilities have integrated quality systems and processes to ensure adherence to cGMP (current Good Manufacturing practices). They are also vertically integrated and can be utilised for large-scale

production of APIs, formulations in various dosage forms rapidly. We make continuous investments in upgradation of manufacturing facilities with special emphasis on deploying advanced machinery and adopting latest technologies to comply with 21 CFR. Besides enabling us consistently to produce high quality medicines at an affordable cost, it also helps us in passing through regulatory audits with relative ease. It is these advantages that make us the partner of choice for major global pharmaceutical companies."[101]

274. Indeed, Hetero further describes itself as "a research-driven pharmaceutical company, is committed to the development, manufacturing and marketing of active pharmaceutical ingredients (APIs), intermediates and finished dosages. Today, Hetero is recognized as a world leader in process chemistry, API manufacturing, formulation development, manufacturing and commercialization. Hetero has around 18 state-of-the-art manufacturing facilities, which are cGMP compliant and have been approved by various Ministries of Health and regulatory authorities like US FDA, WHO, MCC - South Africa, MHRA-UK, TGA – Australia, PMDA – Japan, KFDA (Korea) among others. The company has a rich manufacturing product portfolio of over 200 products across a wide range of therapeutic categories. Hetero has a strong global presence in over 120 countries and has been offering API's and generic formulations to partners across the globe. . . . . Hetero, a privately-owned company, is recognized as one of the top 10 companies in the Indian pharmaceutical industry with an annual turnover of US$ 1.2 billion. With a dedication and support of its 15,000 employees, Hetero continues its commitment to manufacture high-quality drugs and save millions of lives across the world."[102]

[101] Hetero, MANUFACTURING CAPABILITIES, https://www.heteroworld.com/manufacturing.php (last accessed June 6, 2019).
[102] Camber, OUR PARENT COMPANY: HETERO, http://camberpharma.com/about-us/hetero (last accessed June 6, 2019).

275. Specifically with respect to its manufacturing of API, Hetero purports to be "proficient in achieving regulatory approvals worldwide of both APIs and formulations. With an integrated quality system to ensure adherence to cGMP practices, Hetero is committed to quality and its manufacturing facilities are approved by global regulatory agencies. In addition, Hetero continues to invest in its state-of-the-art manufacturing facilities and capabilities to ensure that it is able to provide the highest level of quality standards in the pharmaceutical industry."[103]

276. Hetero likewise goes to great lengths in describing its products as the same as the brand drug. It states that its generic drugs are "copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs. . . . . Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market. . . . . To find out if there is a generic equivalent for your brand-name drug, visit FDA.gov to view a catalog of FDA-approved drug products, as well as drug labeling. Since there is a lag time after generic products are approved and they appear in the

[103] Camber, GLOBAL RESOURCES, http://camberpharma.com/global-resources (last accessed June 6, 2019).

"Orange Book", you should also consult the most recent monthly approvals for "First Generics" at FDA.gov."[104]

3. *Torrent Defendants' Warranties*

277. Torrent Pharmaceutical's website states that they, "strongly believe in providing quality medicines at affordable price to the patients. In this quest, primarily, we have inclined ourselves towards safeguarding both the qualitative and quantitative aspects with the help of our robust manufacturing technologies and manufacturing facilities."[105]

4. *Vivimed Labs' Warranties*

278. On its website, Vivimed states, "Our chemistry touches lives. … Vivimed provides high performance products of quality and value to improve the lives of our clients' consumers."

5. *Macleods Defendants' Warranties*

279. On its website, Macleods states, "Macleods has enjoyed rapid growth in the recent years, growing at an average growth rate of over 22% for the past 5 years."[106]

280. The website further states, "Macleods with its experience spanning more than two decades has emerged as a force to reckon with in global pharmaceutical market …. With expertise in range of formulations ranging from tablets to sterile dosage form and from inhalation to novel drug delivery system, Macleods is currently ranked 10th (on mat basis source IMS) in Indian Pharmaceutical Industry and is recognized as one of the fastest growing pharmaceutical company in India. Pioneering efforts of Macleods in providing medications for both chronic and

[104] Camber, ABOUT GENERICS, http://camberpharma.com/generics (last accessed June 6, 2019)
[105] Torrent Pharmaceuticals, MANUFACTURING, http://www.torrentpharma.com/Index.php/site/info/manufacturing (last accessed June 5, 2019).
[106] https://www.macleodspharma.com/.

acute therapy, with world- class state-of-the-art manufacturing facilities approved by various regulatory authorities of many countries and well equipped R&D, analytical and bioequivalence center audited by various regulatory authorities makes Macleods truly a global pharmaceutical company."

6. *Teva Defendants' Warranties*

281. Teva has a "Generics FAQs" on its website.[107] In response to the question "Are generic drugs safe?" Teva states the following:

> A generic drug is bioequivalent to the original innovative drug and meets the same quality standards. The active ingredient, the content, the dosage form and the usage of a generic drug are similar to those of an innovative drug. Generic drugs are essentially the same as the original drug, but are offered at a lower price.

282. In response to the question "How do you ensure generic drug safety, having tried it in only a limited number of patients?" Teva states the following:

> The generic product's active pharmaceutical ingredient (API) is identical to that of the innovative drug, its purity profile is similar and it is found to be bioequivalent; therefore its safety and efficacy are also comparable.

283. Similarly, under the webpage titled "Uncompromising Quality," Teva states that it knows that its products affect patient health. Teva further states that it "guarantee[s] the quality of our products" with through Teva's "impeccable adherence to … [cGMPs][.]"

284. Teva's website states that "Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and

[107] Teva, PRODUCTS, *at* http://www.tevapharm.com/our_products/generic_qa/ (last accessed June 5, 2019).

certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products."[108]

285. According to Teva, "[o]ur manufacturing network is continuously optimized so that our customers can have full confidence in our supply chain. This is enabled by high-volume, technologically-advanced distribution facilities. These facilities allow us to deliver new products swiftly and reliably. We continually review our capabilities and capacity. This ensures that we can consistently deliver best-in-class products. Our customers know that their end-consumers are receiving high-quality healthcare and wellness pharmaceuticals."[109]

286. In a May 16, 2018 catalog of "all Teva and Actavis products," Teva, Actavis, Teva USA, Arrow, and Actavis Pharma all stated that their LCDs were "bioequivalent" to their RLDs.

287. Teva USA's website states, "Teva's commitment to quality is uncompromising and we manufacture according to the highest quality and compliance standards. This focus is evident at every stage of the development and production of our medicines. All of our manufacturing processes are validated and products are tested and certified, using state-of-the-art testing equipment throughout the manufacturing process designed to ensure adherence to the highest quality and compliance standards."[110]

288. Teva USA's Code of Conduct affirms, "To ensure we are in compliance and working in accordance with sound quality principles in our research laboratories, in our clinical trials, and in our manufacturing plants and distribution centers, we adhere to the systems and

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[108] Teva, Company PROFILE: UNCOMPROMISING QUALITY, https://www.tevapharm.com/about/profile/quality_assurance/ (last accessed June 5, 2019).
[109] *Id.*
[110] Teva USA, ABOUT TEVA: QUALITY YOU CAN TRUST, https://www.tevausa.com/About-Teva/article-pages/quality/ (last accessed June 5, 2019).

internal controls for 'Good Operating Practices,' or 'GxP,' including Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP)."[111]

289. Teva USA maintains a Brand-to-Generic Medication Reference on its website.[112] Before its recall of LCDs, this Reference included LCDs and their RLD equivalents.

7. *Warranties Common to All Retail Pharmacy Defendants*

290. Retail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses.

291. By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments from are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy defendants warrant that prescription drugs they sell are of a standard quality.

292. On account of the existence of these strict liability implied warranties, most retail pharmacies secure indemnification from manufacturer defendants for breach of such warranties.

293. Further, each retail pharmacy defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

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[111] Teva USA, TEVA CODE OF CONDUCT, https://www.tevausa.com/About-Teva/article-pages/Code-of-Conduct/ (last accessed June 5, 2019).
[112] Teva USA. PATIENTS: RESOURCES, https://www.tevagenerics.com/patients/resources/ (last accessed June 5, 2019).

8. ***Wholesale Distributor Defendants' Warranties***

294. Each distributor defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

9. ***Repackager and Relabeler Defendants' Warranties***

295. By selling drugs in the stream of commerce, each repackager and relabeler defendant warrants that the generic drugs they sell are same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics.

296. Further, each repackager and relabeler defendant is obligated under the Drug Supply Chain Security Act to quarantine and investigate potentially illegitimate (including adulterated and/or misbranded) drugs.

M. <u>Fraudulent Concealment And Tolling</u>

297. Plaintiffs' and Class Members' causes of action accrued on the date the FDA announced the recall of Defendants' generic LCDs.

298. Alternatively, any statute of limitation or prescriptive period is equitably tolled on account of fraudulent concealment. Defendants each affirmatively concealed from Plaintiffs and other Class Members their unlawful conduct. Each Defendant affirmatively strove to avoid disclosing their knowledge of their and other Defendants' cGMP violations with respect to their LCDs, and of the fact that their LCDs were adulterated and/or misbranded and contaminated with nitrosamines, and were not the same as their RLDs.

299. For instance, no Defendant revealed to the public that their LCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in December 2018.

300. Each Defendant continued to represent and warrant that their generic LCDs were the same as and therapeutically interchangeable with their RLDs.

301. Because of this, Plaintiffs and other Class Members did not discover, nor could they have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiffs and Class Members into believing that the prices paid for their LCDs were appropriate for what they believed to be non-adulterated or misbranded drugs despite their exercise of reasonable and ordinary diligence.

302. As a result of each Defendants' affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiffs and other Class Members has been tolled. Plaintiffs and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiffs were unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time so as to enable this complaint to be filed sooner.

V. CLASS ACTION ALLEGATIONS

303. Plaintiffs bring this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3) against Defendants on their own behalf and on behalf of the Nationwide Class defined below:

> All individuals and entities in the United States and its territories and possessions who paid any amount of money for a losartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.

304. The Nationwide Class has two sub-classes:

> All consumers in the United States and its territories and possessions who paid any amount of money for a losartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant.
>
> All TPPs in the United States and its territories and possessions that paid any amount of money for a losartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose, Wholesaler, or Repackager/Relabeler Defendant.

305. Plaintiffs allege additional sub-classes for all individuals and TPPs in each State, territory, or possession – or combination(s) of States, territories, or possessions to the extent class members from these jurisdictions can be grouped together for purposes of class treatment – who paid any amount of money out of pocket for a losartan-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant. These include but are not limited to the following:

a. Plaintiff Ira Sanders seeks to represent a North Carolina subclass and/or subclass(es) of states with similar applicable laws to North Carolina.

b. Plaintiffs Solomon Zeller, Rosa Burton, Glenn Roddey, Helen Johnson, and Thomas Ambrose seek to represent a Florida subclass and/or subclass(es) of states with similar applicable laws to Florida.

c. Plaintiff Delphine Harris seeks to represent a Texas subclass and/or subclass(es) of states with similar applicable laws to Texas.

d. Plaintiff Damita Owens seeks to represent a New York subclass and/or subclass(es) of states with similar applicable laws to New York.

e. Plaintiffs Donald Melton, Eugene Tonkovic, and Rosie Roberts seek to represent a Missouri subclass and/or subclass(es) of states with similar applicable laws to Missouri.

f. Plaintiff William Kolacek and David Gipson seek to represent an Illinois subclass and/or subclass(es) of states with similar applicable laws to Illinois.

g. Plaintiff John Cox seeks to represent an Arizona subclass and/or subclass(es) of states with similar applicable laws to Arizona.

h. Plaintiff Darlene Hugg McCauley seeks to represent an Arkansas subclass and/or subclass(es) of states with similar applicable laws to Arkansas.

i. Plaintiff Jean Ellen Thomas seeks to represent a Virginia subclass and/or subclass(es) of states with similar applicable laws to Virginia.

j. Plaintiff La'Vette Howard seeks to represent a Louisiana subclass and/or subclass(es) of states with similar applicable laws to Louisiana.

k. Plaintiff Dominick J. Nicastro, Sr. seeks to represent a New Jersey subclass and/or subclass(es) of states with similar applicable laws to New Jersey.

l. Plaintiffs Deborah A. Payne and Joseph Glenn Cummings seek to represent a Mississippi subclass and/or subclass(es) of states with similar applicable laws to Mississippi.

m. Plaintiff Alicia Degracia seeks to represent a California subclass and/or subclass(es) of states with similar applicable laws to California.

n. Plaintiff Patricia Bellin seeks to represent a Wisconsin subclass and/or subclass(es) of states with similar applicable laws to Wisconsin.

o. Plaintiff Lorna Anderson-Dawes seeks to represent a Pennsylvania subclass and/or subclass(es) of states with similar applicable laws to Pennsylvania.

p. Plaintiff Kevin Stolte seeks to represent an Iowa subclass and/or subclass(es) of states with similar applicable laws to Iowa.

q. Plaintiff Gary Roark seeks to represent a Ohio subclass and/or subclass(es) of states with similar applicable laws to Ohio.

r. Plaintiff Argyre S. Patras seeks to represent a Washington subclass and/or subclass(es) of states with similar applicable laws to Washington.

s. Plaintiffs reserve the right to amend this Complaint to add additional class representatives as appropriate or necessary for additional sub-classes for one or more states.

306. Collectively, the foregoing Nationwide Class and its sub-classes are referred to as the "Class."

307. Excluded from the Class are: (a) any judge or magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

308. Plaintiffs reserve the right to narrow or expand the foregoing class definition, or to create or modify subclasses as the Court deems necessary.

309. Plaintiffs meet the prerequisites of Rule 23(a) to bring this action on behalf of the Class.

310. **Numerosity**: While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of valsartan consumers

nationwide. The Class Members are therefore so numerous that joinder of all members is impracticable.

311. **Commonality**: Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant made express or implied warranties of "sameness" to Plaintiffs and Class Members regarding their generic LCDs;

b. Whether each Defendant's LCDs were in fact the same as their RLDs consistent with such express or implied warranties;

c. Whether each Defendant's LCDs were contaminated with NDEA, NMBA or similar contaminants;

d. Whether each Defendant's LCDs containing NDEA, NMBA or similar contaminants were adulterated and/or misbranded;

e. Whether Defendants violated cGMPs regarding the manufacture of their LCDs;

f. Whether each Defendant falsely claimed that its LCDs were the same as their RLDs and thus therapeutically interchangeable;

g. Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;

h. Whether Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;

i. Whether a common damages model can calculate damages on a class-wide basis;

j. When Plaintiffs' and Class Members' causes of action accrued; and

k. Whether Defendants fraudulently concealed Plaintiffs' and Class Members' causes of action.

312. **Typicality**: Plaintiffs' claims are typical of Class Members' claims. Plaintiffs and Class Members all suffered the same type of economic harm. Plaintiffs have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as the claims of all other Class Members.

313. **Adequacy of Representation**: Plaintiffs are committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation. Accordingly, Plaintiffs and their counsel will fairly and adequately protect the interests of Class Members. Plaintiffs' claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiffs have no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

314. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

315. The requirements of Rule 23(b)(3) are met. The common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues would not be efficient, timely or proper. Judicial resources would be unnecessarily depleted by resolution of

individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in inconsistent relief for similarly situated Plaintiffs. Plaintiffs' counsel, highly experienced in pharmaceutical litigation, consumer fraud litigation, class actions, and federal court litigation, foresee little difficulty in the management of this case as a class action.

FIRST CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

316. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

317. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

318. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs and the other Class members purchased the LCDs. The terms of the contract include the promises and affirmations of fact made by Defendants on the LCDs' packaging and through marketing and advertising, including that the product would be bioequivalent to the name-brand medication, and would be of same "quality" and have the same safety and efficacy profile as the RLD. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and the members of the Class and Defendants.

319. Each Defendant expressly warranted that its LCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically equivalent to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

320. Each Defendant sold LCDs that they expressly warranted were compliant with cGMP and not adulterated or misbranded.

321. Each Defendant's LCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

322. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

323. At the time that each Defendant marketed and sold its LCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members including but not limited to express representations made in referring to their LCDs as losartan, losartan potassium, or losartan HCTZ.

324. Each Defendant breached its express warranties with respect to its LCDs as they were not of merchantable quality, were not fit for their ordinary purpose, and did not comply with cGMP and was adulterated and misbranded.

325. Plaintiffs and each member of the Class would not have purchased the LCDs had they known these drugs were not the same as the RLD, did not contain the same ingredients, did not have the same safety and efficacy profile of the RLD, and contained NDEA and NMBA.

326. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the LCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value.

SECOND CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

327. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

328. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

329. Each Defendant expressly warranted that its LCDs were fit for its ordinary use, i.e., as an FDA-approved generic pharmaceutical that is therapeutically to and interchangeable with their RLDs. In other words, Defendants expressly warranted that their products were the same as their RLDs.

330. Each Defendant sold LCDs that they expressly warranted were compliant with cGMP and/or not adulterated and/or misbranded.

331. Each Defendant's LCDs did not conform to each Defendant's express representations and warranties because the product was not manufactured in compliance with cGMP and was adulterated and misbranded.

332. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code. Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code. Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code. Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev.

Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

333. At the time that each Defendant marketed and sold its LCDs, they recognized the purposes for which the products would be used, and expressly warranted the products were the same as their RLDs, and cGMP compliant and not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiffs and other Class Members, including but not limited to express representations made in referring to their LCDs as losartan, losartan potassium, or losartan HCTZ.

334. Each Defendant breached its express warranties with respect to its LCDs as they were not of merchantable quality, were not fit for its ordinary purpose, and did not comply with cGMP and were adulterated and misbranded.

335. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants' LCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

336. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

337. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

338. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq*.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code

Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

339. Each Defendant was a merchant within the meaning of the above statutes.

340. Each Defendant's LCDs constituted "goods" or the equivalent within the meaning of the above statutes.

341. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit LCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

342. Each Defendant knew or should have known that its LCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that their LCDs were of merchantable quality and fit for that purpose.

343. Each Defendant breached its implied warranty because each Defendant's LCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

344. Plaintiffs and other Class members purchased the LCDs in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

345. The LCDs were not altered by Plaintiffs or Class members.

346. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'

LCDs they purchased was so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

347. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

348. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

349. At all times relevant all fifty States and the District of Columbia and Puerto Rico have codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Ann. Art. § 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. §

1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, *et seq.*; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314 and Wyo. Stat. § 34.1-2-314.

350. Each Defendant was a merchant within the meaning of the above statutes.

351. Each Defendant's LCDs constituted "goods" or the equivalent within the meaning of the above statutes.

352. Each Defendant was obligated to provide Plaintiffs and other Class Members reasonably fit LCDs for the purpose for which the product was sold, and to conform to the standards of the trade in which Defendants are involved such that the product was of fit and merchantable quality.

353. Each Defendant knew or should have known that its LCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs (or is strictly liable in the event of lack of actual or constructive knowledge), and impliedly warranted that same was of merchantable quality and fit for that purpose.

354. Each Defendant breached its implied warranty because each Defendant's LCDs were not of merchantable quality, nor fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.

355. As a direct and proximate result of each Defendant's breach of implied warranty, Plaintiffs and other Class Members have been injured and suffered damages, in that Defendants'

LCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have significantly diminished or no intrinsic market value.

FIFTH CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

356. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

357. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

358. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

359. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

360. Each Defendant expressly or impliedly warranted their LCDs as alleged in the First and Second Causes of Action.

361. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

362. No Defendant has acted on the opportunity to cure its failure with respected to its warranted LCDs.

363. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SIXTH CAUSE OF ACTION
MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. § 2301, *ET SEQ.*
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

364. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

365. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

366. Each Defendant is a "warrantor" within the meaning of the Magnuson-Moss Warranty Act.

367. Plaintiffs and other Class Members are "consumers" within the meaning of the Magnuson-Moss Warranty Act.

368. Each Defendant expressly or impliedly warranted their LCDs as alleged in the First and Second Causes of Action.

369. Under 15 U.S.C. § 2310(d)(1), Plaintiffs and Other Class Members were "damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." 15 U.S.C. § 2310(d)(1). Plaintiffs sue pursuant to this section to recover money damages and for legal and equitable relief on behalf of itself and the Class Members.

370. No Defendant has acted on the opportunity to cure its failure with respected to its warranted LCDs.

371. Likewise, pursuant to 15 U.S.C. § 2310(d)(2), upon prevailing in this action, Plaintiffs are entitled to receive an award of attorneys' fees and expenses and pray for the same.

SEVENTH CAUSE OF ACTION
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

372. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

373. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

374. Defendants affirmatively misrepresented material facts including, *inter alia*, that their LCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

375. Defendants omitted material facts including, *inter alia*, that their LCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

376. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' LCDs – products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMPs and/or were adulterated and/or misbranded. Plaintiffs and other Class Members would not have purchased Defendants' LCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' LCDs had they known the truth because Defendants' LCDs were illegally manufactured, illegally imported, illegally distributed, and

illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

377. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

378. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' LCDs.

379. Defendants' misrepresentations and omissions were material.

380. Defendants' actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

381. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' LCDs.

382. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' LCDs.

383. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated, to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' LCDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

384. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

EIGHTH CAUSE OF ACTION
FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND CONCEALMENT)
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

385. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

386. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

387. Defendants affirmatively misrepresented material facts including, *inter alia*, that their LCDs were therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded.

388. Defendants omitted material facts including, *inter alia*, that their LCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved.

389. Defendants' actions had the effect of fraudulently inducing customers to pay in whole or in part for Defendants' LCDs – product which Defendants knew or should have known was not therapeutically equivalent to their RLDs and did not comply with GMPs and were adulterated and misbranded. Plaintiffs and other Class Members would not have paid some or all of the amounts they paid for Defendants' LCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' LCDs had they known the truth because Defendants' LCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.

390. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.

391. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' LCDs.

392. Defendants' misrepresentations and omissions were material.

393. Defendants actively concealed their misrepresentations and omissions from the Class, government regulators, and the public.

394. To the extent applicable, Defendants intended their misrepresentations and omissions to induce Plaintiffs and other Class Members to pay for Defendants' LCDs.

395. But for these misrepresentations and omissions, Plaintiffs and other Class Members would have not have paid for Defendants' LCDs.

396. To the extent applicable, Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each Class member, including through product labeling and other statements by Defendants. No reasonable consumer would have paid what they did for Defendants' LCDs but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

397. Plaintiffs and other Class Members were damaged by reason of Defendants' misrepresentations and omissions alleged herein.

NINTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

398. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

399. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

400. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its LCDs.

401. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its LCDs.

402. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its LCDs.

403. Each Defendant's statements were false at the time the misrepresentations were made (or at the time omissions were not made).

404. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's LCDs.

405. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

406. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for LCDs.

407. Each Defendant intended its misrepresentations or omissions to induce Plaintiffs and Class members to make purchases of LCDs, or had reckless disregard for same.

408. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have made purchases of Defendants' LCDs.

409. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

410. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

TENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION AND OMISSION
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

411. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

412. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

413. Each Defendant had or undertook a duty to accurately and truthfully represent to the quality, nature, and characteristics of its LCDs.

414. Each Defendant failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the quality, nature, and characteristics of its LCDs.

415. Each Defendant negligently misrepresented or omitted facts regarding the quality, nature, and characteristics of its LCDs.

416. Each Defendant's statements were false at the time the misrepresentations were made (or at the time of the omissions).

417. Each Defendant knew, or reasonably should have known, that its representations alleged herein were materially false or misleading, or that omission of material facts rendered such representations false or misleading. Each Defendant also knew, or had reason to know, that its misrepresentations and omissions would induce Class members to make purchases of each Defendant's LCDs.

418. As a direct and proximate result of each Defendant's acts and omissions described herein, Plaintiffs and other Class Members have suffered harm, and will continue to do so.

419. Each Defendant's misrepresentations or omissions were material and a substantial factor in Plaintiffs' and other Class Members' paying for LCDs.

420. Each Defendant intended its misrepresentations or omissions to induce Plaintiff and Class members to make purchases of LCDs, or had reckless disregard for whether they would do so.

421. But for these misrepresentations (or omissions), Plaintiffs and other Class Members would not have purchased Defendants' LCDs.

422. Plaintiffs and other Class Members were justified in relying on Defendants' misrepresentations or omissions. The same or substantively identical misrepresentations were communicated, and/or the same or substantively identical omissions were not communicated, to each Class Member.

423. Plaintiffs and other Class Members were damaged by reason of each Defendant's misrepresentations or omissions alleged herein.

ELEVENTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

424. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

425. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

426. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vermont's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

427. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

428. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

429. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

TWELFTH CAUSE OF ACTION
VIOLATION OF STATE CONSUMER PROTECTION LAWS (INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

430. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

431. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

432. Each Defendant has violated the consumer protection statutes as follows:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Arizona Rev. Stat. § 44-1522, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

e. Defendants have violated the California Unfair Competition Law by engaging in unfair or deceptive acts or practices in violation of Cal. Bus. Prof. Code § 17200, *et seq.*;

f. Defendants have violated the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.*;

g. Defendants have violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. State 10-1-392, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation 815 ILCS 505/1, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code Ann. § 714H, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vermont's Mo. Rev. Stat. § 407.0 10, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 350, et seq.;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

uu. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

vv. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-11-1, *et seq.*;

ww. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. Tit. 9, § 2451, *et seq.*;

xx. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

yy. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

zz. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

aaa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*;

bbb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*; and

ccc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 23 L.P.R.A. § 1001, *et seq.*, the applicable statute for the Commonwealth of Puerto Rico.

433. Each Defendant's conduct constitutes trade or commerce or other actionable activity within the meaning of the above statutes.

434. Each Plaintiff and other Class Member is a consumer or person aggrieved by Defendants' misconduct within the meaning of the above statutes.

435. To the extent applicable, each Defendant knew, intended, or should have known that their fraudulent and deceptive acts, omissions, or concealment would induce reliance and that reliance can be presumed under the circumstances. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and other Class Members have suffered damages– an ascertainable loss – in an amount to be proved at trial.

THIRTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

436. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

437. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

438. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' LCDs.

439. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' LCDs were adulterated and misbranded, their distribution and sale in the United States was illegal.

440. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' LCDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

441. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FOURTEENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

442. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

443. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

444. As alleged herein, Defendants were unjustly enriched at the expense of Plaintiffs and other Class Members by virtue of the latter's paying for Defendants' LCDs.

445. Defendants profited immensely from introducing a carcinogen into the United States for human consumption. On top of that, because Defendants' LCDs were adulterated and/or misbranded, their distribution and sale in the United States was illegal.

446. Plaintiffs and other Class Members were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' LCDs. It would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation obtained from Plaintiffs and other Class Members as a result of their wrongful conduct alleged in this Complaint.

447. Plaintiffs and other Class Members are entitled to seek and do seek restitution from Defendants as well as an order from this Court requiring disgorgement of all profits, benefits, and other compensation obtained by Defendants by virtue of its wrongful conduct.

FIFTEENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

448. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

449. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

450. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its LCDs.

451. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the LCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

452. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of LCDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its LCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were

adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

453. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own LCDs. Each Defendant knew that ignoring the manufacturing issues surrounding its LCDs would damage Plaintiffs and the Class and increase its own profits.

454. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its LCDs complied with cGMPs and was not adulterated or misbranded.

455. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its LCDs.

456. Each Defendant breached duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

457. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SIXTEENTH CAUSE OF ACTION
NEGLIGENCE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

458. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

459. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

460. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its LCDs.

461. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the LCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

462. Each Defendant owed a duty to care to Plaintiffs and the Class because they were the foreseeable, reasonable, and probable user of LCDs and victim of each Defendant's fraudulent and deceptive activities. Each Defendant knew, or should have known, that its LCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and were adulterated and misbranded, and each was in the best position to uncover and remedy these shortcomings.

463. Each Defendant failed to do this. Each Defendant inadequately oversaw the manufacture and sale of its own LCDs. Each Defendant knew that ignoring the manufacturing issues surrounding its LCDs would damage Plaintiffs and the Class and increase its own profits.

464. Each Defendant maintained or should have maintained a special relationship with Plaintiffs and the Class, as they were obligated to ensure that its LCDs complied with cGMPs and were not adulterated or misbranded.

465. Each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class. Each Defendant's misconduct included, but was not limited to, failing to oversee actions taken in the manufacture and sale of its LCDs.

466. Each Defendant breached the duties owed to Plaintiffs and the Class by failing to exercise reasonable care sufficient to protect the interests and meet the needs of Plaintiffs and the Class.

467. As a direct and proximate result of each Defendant's negligent, and possibly grossly negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

SEVENTEENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS AGAINST ALL DEFENDANTS)

468. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

469. This cause of action is alleged on behalf of consumer Class Members against all Defendants.

470. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its LCDs.

471. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the LCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

472. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards.

473. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

474. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

475. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

EIGHTEENTH CAUSE OF ACTION
NEGLIGENCE PER SE
(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)

476. Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein.

477. This cause of action is alleged on behalf of TPP Class Members against all Defendants except Pharmacy Defendants, and to the extent applicable law permits non-consumers to assert this cause of action.

478. Each Defendant owed a duty to Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its LCDs.

479. Each Defendant owed a duty to Plaintiffs and the Class to ensure that the LCDs it sold in the United States were therapeutically equivalent to their RLDs and complied with cGMPs and were not adulterated or misbranded.

480. Each Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted or adheres to federal cGMP and adulteration standards.

481. Each Defendant failed to comply with federal cGMPs and federal adulteration standards.

482. As a result of each Defendant's failures to do so, each Defendant's own actions and inactions created a foreseeable risk of harm to Plaintiffs and the Class.

483. As a direct and proximate result of each Defendant's negligent conduct, Plaintiffs and the Class has suffered injury and are entitled to damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following judgment:

1) An order certifying this action as a class action;

2) An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;

3) A declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

4) An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

5) Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for the LCDs; the costs to replace or return LCDs because of recalls; and/or the increases in the amounts paid for non-adulterated, non-misbranded, LCDs in the wake of the recalls;

6) An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

7) An award of statutory penalties to the extent available;

8) Interest as provided by law, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

9) Such other and further relief as this Court may deem just, equitable, or proper.

JURY DEMAND

Plaintiffs respectfully request a trial by jury on all causes of action so triable.

Dated: 1/15/2021

Respectfully Submitted,

/s/ Ruben Honik
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